

A Comparative Study Of Efficacy Of Intracervical Prostaglandin E2 Gel And Intracervical Foley's Catheter For Pre- Induction Cervical Ripening

Dr. V.Revathi, M.D., D.G.O¹, Dr. I. Archana, M.B.B.S²

1. Department Of Obstetrics And Gynaecology Siddhartha Medical College
Dr Ntr University Of Health Sciences, Vijayawada India. 2. Department Of Obstetrics And Gynaecology
Siddhartha Medical College
Dr Ntr University Of Health Sciences, Vijayawada India.

Abstract: Induction of labour with the aim of achieving vaginal delivery has become a routine practice. The successful outcome of induction of labour depends upon the state of cervix.

Aims and objectives: The aim of this study is to compare the safety and efficacy of intracervical PGE2 gel and intracervical foley's catheter in pre-induction cervical ripening and to evaluate the cost-effectiveness and reliability of these methods

Study design: A randomized prospective study was conducted in the department of obstetrics and gynaecology in Government General hospital, Vijayawada. One hundred antenatal women at term were randomly allocated to two groups to receive intracervical foley's catheter and prostaglandin E2 gel. Bishop's score is assigned before induction and reassigned after 6 hrs. Labour was augmented if required.

Results : Statistical analysis was done using chi-square and t-test. The parameters observed were improvement in Bishop's score, (8.62 ± 1.563 in foley's catheter and 8.68 ± 1.69 in prostaglandin E2 gel groups), the mean induction delivery interval (foley's group is 18.49 ± 6.59 hrs and in prostaglandin E2 gel group is 17.6 ± 6.52) hrs. The difference in mode of delivery, appgar score in both the groups is not statistically significant at p value > 0.05

Conclusion : From this study it can be concluded that foley's catheter is equally effective method for pre-induction cervical ripening as prostaglandin E2 gel

Keywords : Prostaglandin E2 Gel, Intracervical Foley's catheter, induction of labour

I. Introduction

Planned pre induction cervical ripening and induction of labour has become an established part of modern obstetric practice. One of the factors that influences successful induction of labour is the state of the uterine cervix. If the cervix is unripe (closed, unaffaced, firm), Bishop's score¹ less than 6, then the conventional method of induction of labour by surgical amniotomy is technically difficult. Titration with intravenous Oxytocin results in prolonged labour with risks of maternal and foetal complications, unsuccessful inductions, unnecessarily increasing the rates of cesarean section. Active induction policy for special indications after 37 weeks has reduced the perinatal mortality along with other factors like good intrapartum care and specialized neonatal intensive care services.

The rate of Labour induction in India continues to rise significantly for all gestational ages (11.4% in India). Foley's catheter : The mechanical action of Foley's catheter strips the fetal membranes from the lower uterine segment and causes release of phospholipase A, prostaglandins and cytokines directly into the vagina which is associated with cervical dilatation.

Prostaglandin E2 gel exogenous local application results in cervical ripening by softening the cervix, increasing the activity of collagenase, glycosaminoglycans, hyaluronic acid and relaxes the smooth muscle of cervix.

II. Methods

Study design : This is a prospective study
Informed consent was obtained before enrollment

Study setting and population : The study was conducted in the Department of Obstetrics and Gynaecology in Government General Hospital, Vijayawada, India. One Hundred antenatal women were randomly selected into two groups.

Inclusion criteria : Completed 37 weeks of pregnancy ,singleton pregnancy, primi or multigravida, age greater than 18 yrs , cervix Bishop's Score < 6

Exclusion Criteria : Less than 37 weeks gestational age, multiple pregnancy, non-vertex presentation, placenta previa , premature rupture of membranes.

III. Methodology

Patients needed for induction of labour were categorized into 2 groups of 50 cases each

Group 1 : Cervical ripening by Foley’s catheter

Group 2 : Cervical ripening by PGE2 gel

Group 1 : After allotting Bishop’s score Foley’s catheter of no. 18 with 30 ml balloon was inserted directly into endocervical canal beyond the internal os, extra amniotically and inflated with 30 ml distilled water. Catheter was placed on traction by taping it to medial aspect of thigh. Fetal heart rate, uterine contractions were monitored. Foley’s catheter if spontaneously expelled, Bishop’s score reassigned. If not expelled in 12 hours, catheter is adjusted to maintain continued traction. Bishop’s score once again reassigned after 12 hours case may be taken as failure if patient does not set into active labour within 24 hours.

Group 2 : After allotting Bishop’s score, 0.5 mg of PGE2 gel was administered intracervically. The patient was instructed to lie in left lateral position following gel administration for half an hour. Later fetal heart rate, uterine contractions were monitored. Then patient is made ambulatory. After 6-8 hours per vaginal examination was done and Bishop’s Score assigned. If Bishop’s score was found favourable, oxytocin induction or augmentation was done. If not favourable Bishop’s score was once again reassigned after 12 hours. Any other method are reinstallation of gel is done if patient does not set into active labour in 24 hours, taking as failure for this method.

IV. Observation And Results

Comparison of intracervical foley’s catheter and intracervical prostaglandin E2 gel for pre-induction cervical ripening

Table 1 : Preinduction Bishop’s Score

Bishop’s Score	Foley’s Group	Prostaglandin E2 Gel	Total	Statistical significance
1-3	38	40	78	X ² =0.2331 df = 1 p>0.05
4-5	12	10	22	
	50	50	100	
Mean±sd	2.60±1.55	2.86±1.57		T = 0.1847 P > 0.85 NS

The Chi-square statistic is 0.2331 the p value is 0.629235. The result is not significant at p>0.05. The mean pre induction Bishop’s Score in foley’s group is 2.60 ± 1.55 and prostaglandin E2 gel group is 2.86±1.57 both the study groups are comparable. The differences in mean pre induction Bishop’s score is also not statistically significant (student ‘t’ test = 0.184744, p value is not significant at p>0.05, ns).

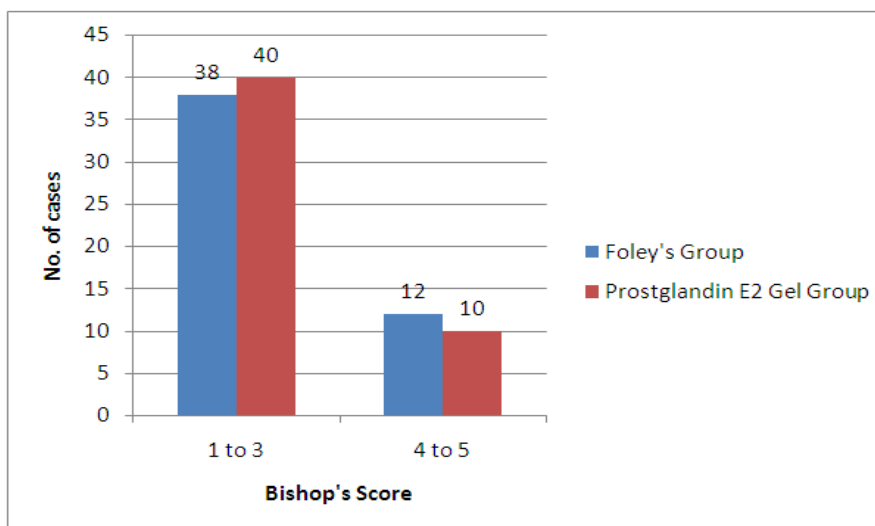


Table – 2 : Comparison of Post Induction Bishop's Score;

Bishop's Score	Foley's Group	PG E ₂ Gel group	Total	Statistical Significance
<6	5	4	9	X ² = 0.1221 df = 1 P > 0.05 ns
>6	45	46	91	
	50	50	100	
Mean ± sd	8.62 ± 1.56	8.68 ± 1.69		T = 0.451, P > 0.5 ns

The chi-square statistic is 0.1221, p value is 0.726768 the p value is not significant at p > 0.05. The mean improvement of Bishop's score in Foley's group is 8.62 ± 1.56 prostaglandin E₂ Gel group is 8.68 ± 1.69 the difference of mean improvement of Bishop's score is studied by student 't' Test t = 1.451829, p value is 0.652391. the result is not significant at p > 0.05.

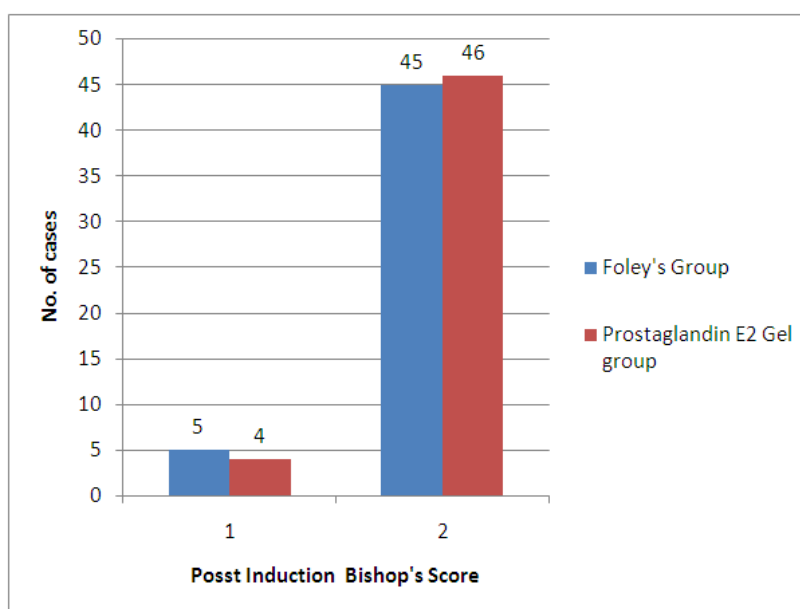


Table -3 : Comparison of Induction - Delivery Interval:

Study Group	Mean induction-delivery Interval in Hours. (Mean ± sd)	Statistical analysis
Foley's Group	18.49 ± 6.59	T = 0.64 ; P > 0.05 ns
Prostaglandin E ₂ Gel Group	17.6 ± 6.52	

The mean induction to delivery interval in Foley's group is 18.49 ± 6.59 hrs. and Prostaglandin E₂ Gel group is 17.6 ± 6.52. The difference is studied by student't' test (t = 0.64, P > 0.05, ns), not statistically significant.

Table -4 : Comparison of Mode of delivery

Mode of Delivery	Foley's Group	PGE ₂ Gel group	Total	Statistical Significance
Vaginal Delivery	34	36	70	X ² = 0.2079 df = 3 P > 0.05 Ns
Lower segment cesarean section	12	10	22	
Forceps Delivery	3	3	6	
Vacuum Extraction	1	1	2	
	50	50	100	

The chisquare statistic is 0.2079, p value is 0.648418 the result is not significant at p > 0.05. The differences in the mode of delivery, is both the study groups are compared, the difference is not statistically significant

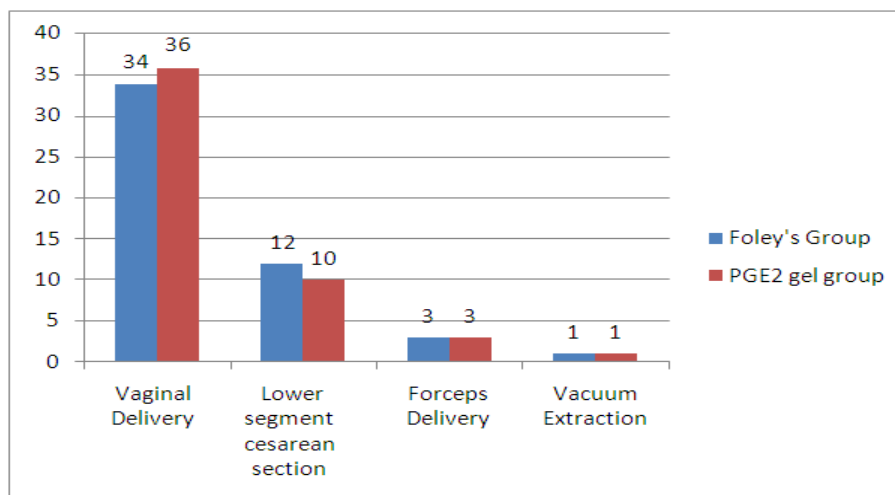
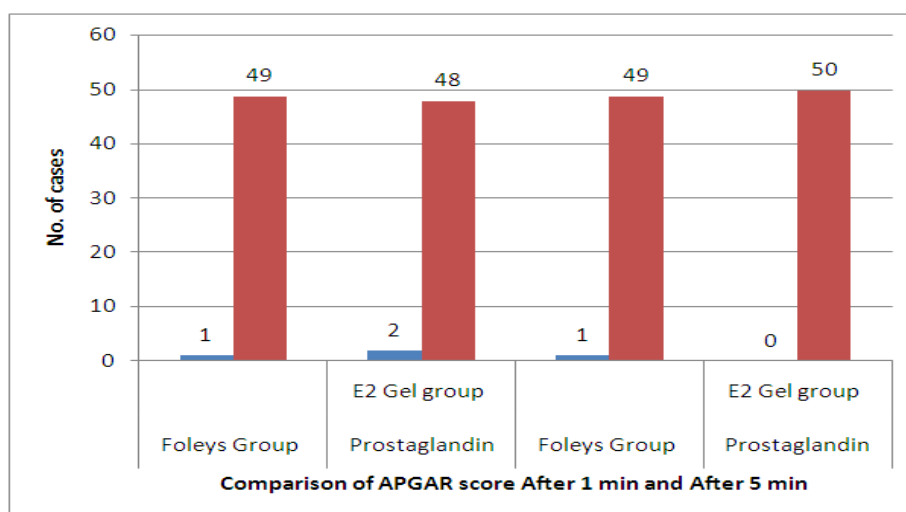


Table – 5 COMPARISON OF APGAR SCORE AFTER '1* MIN AND AFTER '5' MIN.

APGAR Score	1 Min			5Min		
	Foleys Group	Prostaglandin E2 Gel group	Total	Foleys Group	Prostaglandin E2 Gel group	Total
6-7	1	2	3	1	0	1
8-10	49	48	97	49	50	99
	50	50	100	50	50	100

The difference in APGAR score in both the study groups is not statistically significant ($\chi^2 = 0.3436$, P value is 0.557734, the value is not significant at $p > 0.05$, ns).



V. Discussion

Cervical ripening is normal prelude to the onset of myometrial contractions. It is important to choose a method which will ripen the cervix and have a successful outcome of planned induction of labour.

In my study both foley's and prostaglandin E2 gel have been successfully effective in both primi and multi gravid in achieving cervical ripening and improving Bishop's score and promoting changes, resembling physiological events of ripening and labour

Foley's catheter can also be used in cases of Bronchial Asthma, increased intra ocular pressure and previous LSCS. Foley's catheter, thus provides better alternative for preinduction cervical ripening.

M. Ezimokal and Nwabinelli conducted comparative study for preinduction of labour with Foley's catheter Vs prostaglandin E2 gel group. The preinduction bishop score is 2.8 ± 0.8 in Foley's and 1.9 ± 0.9 years in prostaglandin E2 gel group. The preinduction bishop score in my study Foley's group is 2.6 ± 1.55 and prostaglandin E2 gel group is 2.86 ± 1.57 is comparable to above study.

SCISCIONE AC ET AL conducted a prospective, randomized comparison study of Foley's Catheter V2 Prostaglandin E2 gel for preinduction cervical ripening. The post induction bishop score in Foley's group is 6.5 ± 1.63 , and prostaglandin E2 group 5.1 ± 2.3 . In my study the post induction bishop score in Foley's group is 8.62 ± 1.563 and prostaglandin E2 gel group is 8.68 ± 1.69 .

VERMA ET AL in 1982 conducted a study for preinduction cervical ripening with Foley's catheter, in their study the vaginal deliveries 60%, forceps 22%, caesarean Section 18%. In my study Foley's group : 68% vaginal deliveries, 6% forceps, 2% vacuum extraction, 24% caesarean section and prostaglandin E2 gel group, 72% vaginal deliveries, 6% forceps, 2% vacuum extraction and 20% caesarean section.

ONGER R CONNOR et al conducted a randomized prospective study for preinduction cervical ripening with Foley's catheter Vs prostaglandin E2 gel group. The mean induction delivery interval in Foley's group is 16.0 ± 1.7 hrs. and prostaglandin E2 gel group is 21.5 ± 3.2 hrs. in my study the mean induction delivery interval in Foley's group is $18.49\text{hrs} \pm 6.59$ and prostaglandin E2 gel group is 17.6 ± 6.52 hrs.

VI. Conclusion

The aim is to study the efficacy of intra cervical Foley's catheter versus intra cervical prostaglandin E2 gel in pre-induction cervical ripening. 100 cases attending the labour room and antenatal ward which need pre induction cervical ripening are randomly selected. Both the groups are matched and were compared in post induction improvement in Bishop's Score mode of delivery neonatal outcome in term of apagar score after 1 min and 5 min, Intrapartum complications, mean induction delivery interval.

Post induction improvement in Bishop's score in Foley's Group is 8.62 ± 1.563 and prostaglandin E2 gel group is 8.68 ± 1.69 . During the study one case developed rupture of membrane in Foley's group and 2 cases in PGE2 gel group developed PROM. 2 cases developed fetal distress in prostaglandin E2 Gel group.

Mean induction delivery interval in Foley's group is 18.49 ± 6.59 hrs and prostaglandin E2 gel group is 17.6 ± 6.52 hrs. So this study concludes that intra cervical Foley's catheter for preinduction cervical ripening is equally effective and cost effective to intra cervical prostaglandin E2 gel group for pre induction cervical ripening.

References

- [1]. Anthony sciscione et al. 1999 – a prospective randomized comparison of Foley's catheter insertion Vs intracervical PGE2 gel for pre induction cervical ripening *Obstetrics and gynaecology*, November 2001, volume 98, issue 5, part 1, pg ; 751-756.
- [2]. St.onge : *American Journal of obstetrics and gynaecology* 1995, ISSN 0002-9378.
- [3]. Ezlmokhai and Nwabinelli 1980; the use of Foley's catheter ripening the unfavourable cervix prior to induction of labour *British Journal of obstetrics and gynaecology*, 87, 281-286.
- [4]. Bishop's E.H – 1964 – Pelvic scoring for elective induction *obstetrics and gynaecology* 24 : 266-268.
- [5]. A practical guide to obstetrics. Gita Arjun 2013. Pg, 518.
- [6]. St. onge. R.Connor; pre induction cervical ripening A comparison of intra cervical PGE2 gel Vs Foley's catheter *American Journal obstetrics and gynaecology*, 1995 ; 172-657.