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# A COMPARATIVE ANALYSIS OF ORAL PROSTAGLANDIN E2, INTRACERVICAL PROSTAGLANDIN E2 AND INTRACERVICAL EXTRA-AMNIOTIC FOLEY'S CATHETER IN CERVICAL RIPENING FOR INDUCTION OF LABOUR

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#### **ABSTRACT**

**BACKGROUND** 

Induction of labour is one in which pregnancy is terminated artificially any time after the age of viability by a method that aims to secure delivery per vias naturalis either because of any maternal or fetal indications or involving both irrespective of the outcome. Various methods are adopted for converting an unfavourable cervix to favourable one by simple oxytocin infusion, use of cervical balloons, prosta - glandins in oral, intra vaginal and extra-amniotic routes have been by different workers, success remains a major observation and complication and availability of the method is another important consideration.

Use of Foley's catheter by Ezimokhai <sup>30</sup> et al (1980) for cervical ripening prior to induction is very encouraging. The technique is simple and can widely practised in a country like ours.

MATERIAL AND METHOD

Viewed in this context, this prospective study has been undertaken in the Department of O&G, Hitech Medical College and hospital, bhubaneswar from July 2019 to December 2022. The purpose of my study is to compare the efficacy of intra cervical placement of a Foley's balloon catheter, intra cervical prostaglandin E2 & oral Prostaglandin E2 in cervical ripening for induction of labour

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# **RESULT**

On comparing the modes of induction, it was found that Spontaneous labour occurred highest in Primiprost group (51.62%) followed by Cerviprime group (35.48%) & Foley's group (20.96%) but the induction in the form of Artificial rupture of membrane, oxytocin infusion or both subsequent to cervical ripening was highest in Foley's group (79.03%) followed by Cerviprime group (64.5%) & Primiprost group (48.38%) which was statistically significant.

# **CONCLUSION**

Inflated Foley's catheter for priming of an unfavorable cervix is of proved value but the role in inducing uterine contractility is poor. Prostaglandins are very good inducers of labour but they are not free from side effects like failed induction and foetal jeopardy. Cervical ripening with extra amniotic balloon catheter possesses the advantages of simplicity, low cost, reversibility & lack of severe side effects & so seems to be an ideal method for acceptance where prostaglandins are contraindicated or when uterine hyperstimulation should be avoided such as in cases of intra uterine fetal growth retardation, placental insufficiency, asthmatic patients, diabetics and so on.

#### **KEY WORD:**

Induction of labour, prostaglandin, PGE1, PGE2, foley's induction.

#### **INTRODUCTION**

In an ideal world, all pregnancies would go to term, and labor would begin spontaneously. In reality, it is often best to deliver the infant before the onset of natural labor. In making the decision for an early delivery, the physician relies on the clinical stability of the mother and foetus to decide between performing a caesarean section and inducing labor for a vaginal delivery.

Induction of labour is one in which pregnancy is terminated artificially any time after the age of viability by a method that aims to secure delivery per vias naturalis either because of any maternal or fetal indications or involving both irrespective of the outcome. Though the story of induction dates back to the time of Hippocrates, the pioneer of successful induction goes to Theobald. Successful induction of labour was first made possible in 1948 by intravenous oxytocin by him. This transformed the art of obstetrics.

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An often quoted phrase referring to methods of cervical dilatation states that:-

"These include springs, bougies, dilators, roots, stems, catheters, sponges, screws, pliers, bags & balloons. The cervix has been primed from above & rammed open from below. It has been greased, heated, split & shocked. It has been injected, digested & vibrated. It has been anaesthetized, hormonized, narcotized & paralyzed. (Newton 1972) ".

The effectivity of oxytocics counts on the numbers of oxytocic receptors in the myometrium and the status of the uterine out let i.e. cervix. Thus the key to successful induction of labour is proper cervical ripening. Cervical ripening whether physiological or pharmacological is the conversion of the rigid cervical sphincter associated with maintenance of pregnancy to a readily dilating structure so that uterine contractility can affect the birth of the fetus with ease.

Various methods are adopted for converting an unfavourable cervix to favourable one by simple oxytocin infusion, use of cervical balloons, prostaglandins in oral, intra vaginal and extra-amniotic routes have been by different workers, success remains a major observation and complication and availability of the method is another important consideration.

Use of Foley's catheter by Ezimokhai <sup>30</sup> et al (1980) for cervical ripening prior to induction is very encouraging. The technique is simple and can widely practised in a country like ours.

The introduction of prostaglandins in clinical use in this area has not only increased the efficacy in cases with unripe cervix, but also proved to be a very effective oxytocic bridging between the two interlinked components of labour - cervical ripening and uterine contractility.

# MATERIAL AND METHOD

Viewed in this context, this prospective study has been undertaken in the Department of O&G, Hitech Medical College and hospital, bhubaneswar from July 2019 to December 2022. The purpose of my study is to compare the efficacy of intra cervical placement of a Foley's balloon catheter, intra cervical prostaglandin E2 & oral Prostaglandin E2 in cervical ripening for induction of labour.

**INCLUSION CRITERIA:** Following criteria are observed during selection of patients for induction of labour.

- 1. Gestational period from 30-42 wks.
- 2. Primi or multigravida not more than 5 term pregnancy.

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3. Patients should have unfavourable cervix, modified BISHOP'S score between 0-5.

# **EXCLUSION CRITERIA:** The following cases are excluded from study.

- 1. Contracted pelvis & cephalopelvic disproportion.
- 2. Malpresentation
- 3. Medical disorder like Cardiac disease, Diabetes, Renal disease in the mother.
  - 4. Previous caesarean section birth & Hysterotomy scar.
  - 5. Obs. complication like APH, Fetal distress.

DATA ANALYSIS: On completion of the study the data will be analysed to draw conclusion regarding which method of cervical ripening is better,low cost,simple, reversible with minimal side effect & ideal method of acceptance.

# RESULT TABLE-1

CROSS-TAB OF COMPLICATIONS IN DIFFERENT GROUPS

Complication		Cerviprime	Primiprost	Foley's	Total	P Value
None	Count	56	56	60	172	
None	% within row	32.6%	32.6%	34.9%	100.0%	
maternal	Count	2	2	2	6	
tachycardia	% within row	33.3%	33.3%	33.3%	100.0%	0.381
vomitina	Count	4	4	0	8	0.381
vomiting	% within row	50.0%	50.0%	.0%	100.0%	
Total	Count	62	62	62	186	
	% within row	33.3%	33.3%	33.3%	100.0%	

The complications occurred during pre-induction methods in form of maternal tachycardia and vomiting were not statistically significant among the 3 groups however these complications were found only in cerviprime group & Primiprost group whereas Foley's group was free from it..

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TABLE-2
CROSS-TAB OF MODES OF INDUCTION IN DIFFERENT GROUPS

Modes of Induction		cerviprime	Primiprost	Foley's	Total	P value
Spontaneou s labour	Count	22	32	13	67	
	% within row	32.8%	47.8%	19.4%	100.0%	
ARM	Count	8	6	7	21	
AKIVI	% within row	38.1%	28.6%	33.3%	100.0%	
,	Count	22	14	22	58	
Oxytocin	% within row	37.9%	24.1%	37.9%	100.0%	0.016 (signific
ADM   Overt	Count	10	10	20	40	ant)
ARM+Oxyt ocin	% within row	25.0%	25.0%	50.0%	100.0%	
Total	Count	62	62	62	186	
	% within row	33.3%	33.3%	33.3%	100.0%	

The above table shows there were statistically significant differences in modes of induction. Spontaneous delivery occurred maximally in primiprost group followed by cerviprime group and foley's group.

TABLE-3
CROSS-TAB OF MODES OF DELIVERY IN DIFFERENT GROUPS

Modes of delivery		Cerviprime	Primiprost	Foley's	Total	P Value
VD	Count	44	40	58	142	
VD	% within row	31.0%	28.2%	40.8%	100.0%	
LSCS	Count	14	18	4	36	0.002
LSCS	% within row	38.9%	50.0%	11.1%	100.0%	(Signifi-
FORCEPS	Count	4	4	0	8	Cant)
FURCEPS	% within row	50.0%	50.0%	.0%	100.0%	
Total	Count	62	62	62	186	

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Modes of delivery		Cerviprime	Primiprost	Foley's	Total	P Value
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VD	% within row	31.0%	28.2%	40.8%	100.0%	
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EODCEDS	Count	4	4	0	8	Cant)
FORCEPS	% within row	50.0%	50.0%	.0%	100.0%	
Total	Count	62	62	62	186	
	% within row	33.3%	33.3%	33.3%	100.0%	

While comparing among the 3 groups there were statistically significant. Differences in the modes of delivery. However LSCS rate was high in primiprost group (50%) than cerviprime group (38.9%) and foley's group (11.1%). But spontaneous vaginal delivery occurred maximally in foley's group.

TABLE-4
CROSS-TAB OF APGAR SCORE AT 1 MIN. IN DIFFERENT GROUPS

	AR score at 1 min.	Cerviprime	Primiprost	Foley's	Total	P value
	Count	3	6	2	11	
< 6	% within row	27.3%	54.5%	18.2%	100.0%	0.300
	Count	51	48	50	149	0.500
>= 6	% within row	34.2%	32.2%	33.6%	100.0%	(Not significan
	Count	54	54	52	160	t)
Total	% within row	33.8%	33.8%	32.5%	100.0%	

Above table shows that there was no statistical differences of APGAR score at 1 minute among 3 groups. However no. of depressed childs were more in number in Primiprost group than Cerviprime & Foley's groups.

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TABLE-5
CROSS-TAB OF APGAR SCORE AT 5 MIN. IN DIFFERENT GROUPS

APG	AR score at 5 min.	Cerviprime	Primiprost	Foley's	Total	P value
- 6	Count	3	6	2	11	
< 6	% within row	27.3%	54.5%	18.2%	100.0%	0.300
	Count	51	48	50	149	0.00
>=6	% within row	34.2%	32.2%	33.6%	100.0%	(Not
T-4-1	Count	54	54	52	160	significant)
Total	% within row	33.8%	33.8%	32.5%	100.0%	

There was no statistical differences of APGAR score at 5 minutes among patients recruited in Cerviprime, Primiprost & Foley's groups.

TABLE-6
CROSS-TAB OF POST-PARTUM MORBIDITY IN DIFFERENT GROUPS

Post par	Post partum morbidity		Primiprost	Foley's	Total	P Value
Absent	Count	62	62	56	180	
Absent	% within row	34.4%	34.4%	31.1%	100.0%	
Бахгая	Count	0	0	2	2	
Fever	% within row	.0%	.0%	100.0%	100.0%	
UTI	Count	0	0	2	2	0.054
UII	% within row	.0%	.0%	100.0%	100.0%	(Not
DDH	Count	0	0	2	2	signific
PPH	% within row	.0%	.0%	100.0%	100.0%	ant)
Total	Count	62	62	62	186	
Total	% within row	33.3%	33.3%	33.3%	100.0%	

There was non-statistically difference of post partum morbidity in the form of Fever, UTI,PPH, among the 3 groups.

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TABLE-7
CROSS-TAB OF INDUCTION OUTCOME IN DIFFERENT GROUPS

Induction Outcome		Cerviprime	Primiprost	Foley's	Total	P value
No	Count	62	47	62	171	
problem	% within row	36.3%	27.5%	36.3%	100.0%	
Failed	Count	0	13	0	13	0.000
Induction	% within row	.0%	100.0%	.0%	100.0%	(Highly
Prolonged	Count	0	2	0	2	( Highly
Labour	% within row	.0%	100.0%	.0%	100.0%	significant
T-4-1	Count	62	62	62	186	)
Total	% within row	33.3%	33.3%	33.3%	100.0%	

There was statistically significant differences in the form of induction outcome among the 3 groups. No.of Failed induction (13) were highest in primiprost group and also the prolonged labour (2).

TABLE-8
CROSS-TAB OF FOETAL OUTCOME IN DIFFERENT GROUPS

Foetal outcome		Cerviprime	Primiprost	Foley's	Total	P value
NICU	Count	3	6	2	11	
admission	% within row	27.3%	54.5%	18.2%	100.0%	
	Count	51	48	50	149	0.300
Normal	% within row	34.2%	32.2%	33.6%	100.0%	(Not significant)
	Count	54	54	52	160	Significant)
Total	% within row	33.8%	33.8%	32.5%	100.0%	

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The above cross table shows there were no statistically significant differences in the foetal outcome among the 3 groups. NICU admissions were highest in Primiprost group 6 (11.11 %) out of 54 child birth in comparison to Cerviprime group 3(5.55%) out of 54 child birth & Foley's group 2 (3.86%) out of 52 child birth.

# **DISCUSSION**

In the present study of 186 cases requiring termination of pregnancy with unfavorable cervical score, equal number of cases (62) were selected at random & 3 series of works were conducted, 1st series is cervical priming with inflated balloon catheter followed by induction with oxytocin, 2nd series with intra cervical PGE2(0.5mg) Gel & 3<sup>rd</sup> series with oral Primiprost tab(PGE2). Embrey<sup>28</sup> (1976) concluded that success of cervical balloon catheter for induction of labour was more frequent after the estimated date of delivery because he only included at term cases (37-42wks).

Ezimokhai<sup>30</sup> et al (1980) observed in their series of 21 Primigravida, the mean pretreatment & post treatment modified Bishop's score (0-3) & (6.2 $\pm$  2.4) respectively. In this series, the mean scoring before & after priming by Foley's catheter was (3.32  $\pm$ 0.94) & (7.51  $\pm$ 0.88) respectively with the mean increase in Bishop's score was (4.19 $\pm$ 1.00) .These values compared well with their series.

Warke  $^{81XX}$  et,al,1999 observed the preinduction cervical score in 75 patients after ripening with PGE2 gel(0.5 mg). In their study group, the pre treatment Bishop's score & Change in Bishop's score was 2.24 & 7 respectively which are comparable.

Embrey<sup>28</sup> et al (1976) used Foley's catheter to ripen the cervix prior to surgical induction taking the induction onset of labour interval as less than 48hrs. Excluding the interval during which effacement of the cervix was being affected by the balloon & taking only the rupture of the membranes as the onset of labour, success in 48hrs was achieved in 94% of cases, but in their series the improvement was not quantitatively assessed.

Different authors used PGE2 by various routes & by various preparations to ripen the cervix.

Mackenzie<sup>55,56,57</sup> (1977) used 2mg & 5mg PgE2 Gel & observed the cases.

Among all the methods, extra amniotic PGE2& oral PGE2 are proved efficacious for induction of labour. Result of intra cervical Foley's balloon catheter ripening followed by induction is also comparable to PGs.

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In the present study, vaginal delivery was the commonest mode of delivery. Caesarean section rates were 6.45% in Foley's series, 22.58% extra-amniotic PGE2 series and these are comparable to Franchi<sup>43</sup> et al (2000) studies, in which LSCS rate was 14.7% in Foley's compared to 26.5% in PGE2 Group. 13 patients in this series with Foley's catheter priming went into spontaneous labour where as in Ezimokhais<sup>30</sup> observation only 2 patients went to spontaneous labour. In Warke 81XX et,al(1999) studies. LSCS rate was 17.33% with PGE2 gel(intracervical), which is well within the LSCS rate given in all international literature, i.e, 6% - 26.66 %. In St Onge<sup>6</sup> (1995) figure et al in their study found 17.6% delivered by LSCS.

Analyzing the rate of maternal morbidity in postpartum period, only 2 cases each had fever, urinary tract infection and PPH which was not at all attributable to introduction of infection by extra amniotic balloon catheter & Ezimokhai<sup>30</sup> et al (1980) observed the same. Also in Warke <sup>81XX</sup> et,al.(1999) study(PGE2 gel), PPH rate was 4% in the form of Traumatic PPH,1.33% & Atonic PPH, 2.67%.

In PGE2 application in present series, 4 patients developed vomiting & 2 tachycardia relieved afterwards. Though hyper tonicity was not a complication in our series, but Warke <sup>81XX</sup> et,al.(1999)study of 75 patients, maternal adverse events recorded in PGE2 gel group were Vomiting 10.67%, Diarrhoea 10.67% & hyperactivity of uterus in 2.67%. Owen, Carey (in Birmingham, Alabama) et al published a paper doing a meta analysis incorporating 18 studies of 1811 patients who received a single application of at least 5mg PGE2 intra vaginally or 0.5mg intra cervically demonstrated no significant decrease in the overall caesarean section rate (P=0.85). So they concluded that the use of single dose intra cervical PGE2 for cervical ripening has little effect on labour induction. No conclusive proof of neonatal septicemia due to Foley's catheter introduction was found.

Visscher RD, Struyk CD, Visscher HC <sup>81X</sup> reported about the guidelines for the effective induction of labour with oral PGE2. Fifty multiparous patients at 37 weeks or more of gestation with a vertex presentation and a Bishop score of 7 or more had labor induced with oral Prostaglandin E2 tablets. All responded and delivered vaginally. The induction to delivery time averaged 4 hours and 44 minutes. The average number of tablets required was 3.64. Four women experienced nausea and an additional 4 women had some vomiting. Two patients showed hypertonus and 11 had frequent contractions. Many progressed rapidly after they began active labor. There was no evidence of fetal distress. Guidelines are suggested for the use of oral Prostaglandin E2 tablets to adequately control the labor process and prevent hypercontractility.

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In <u>Ang LT& Frith KM</u> <sup>8X</sup> study group, 14 nulliparas and 28 multiparas were induced at term by combined low amniotomy and oral prostaglandin E2 (PGE2) solution. Doses, after a .5 mg test dose, were 1, 1.5, or 2.0 mg at 2-hour intervals. There were 37 successful deliveries, 3 Caesarean sections, and 2 failures, later successful with oxytocin. Induction delivery intervals averaged 12.6 hours in nulliparas and 8.9 hours in multiparas, and were inversely proportional to pelvic score. Fetal distress occurred in 2 cases. No other fetal side effects were reported, but vomiting was frequent (28.5%) and sometimes severe.In this study group of 62 women, failed induction & prolonged labour was 20.96% & 3.22% respectively which was quite significant.

# **SUMMARY**

A total of one hundred eighty six patients with unfavorable cervices (Modified Bishop's Score 0-5) were subjected to ripening with various agents like inflated Foley's catheter, intra cervical (0.5) PGE2 gel & oral (0.5) PGE2 tab of sixty two patients each followed by induction with intravenous oxytocin infusion & amniotomy (reserved at & when required). Pregnancy induced hypertension & its sequels like eclampsia, postdated (prolonged pregnancy) pregnancies, IUGR, Congenital malformations were the possible causes of indication for induction. Majority of the cases in all the 3 series were of age group 20-29yrs. Primigravida comprised of the largest number of cases in all 3 groups and majority of cases were with gestational age 34-38 wks.

The Means of pretreatment cervical score in the three groups were , Cerviprime (3.38  $\pm$  1.07 ), Primiprost (3.16  $\pm$  1.17 )& Foley's ( 3.32  $\pm$  0.93 ). Similarly the Means of Change in Bishop's score in the three groups were, Cerviprime (3.80  $\pm$  1.23 ), Primiprost (3.83  $\pm$  1.20 )& Foley's ( 4.19  $\pm$  1.06).Though there was no statistically significant differences in the change of Bishop's score , Foley's group had highest change among all.

On comparing the modes of induction, it was found that Spontaneous labour occurred highest in Primiprost group (51.62%) followed by Cerviprime group (35.48%) & Foley's group (20.96%) but the induction in the form of Artificial rupture of membrane, oxytocin infusion or both subsequent to cervical ripening was highest in Foley's group (79.03%) followed by Cerviprime group (64.5%) & Primiprost group (48.38%) which was statistically significant.

On analyzing the outcome of induction, Primiprost group had majority of induction failure (20.96%) & prolonged labour(3.22%) among the study groups.

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The mode of delivery contributed a significant impact on all the three study groups. A large no. of normal vaginal deliveries were conducted in Foley's group (93.54 %) in comparison to Cerviprime group (70.96%) & Primiprost group (64.5%) but the Primiprost group contributed maximum number of LSCS (29.03%) among the three groups.

On comparing the Means of induction delivery interval (IDI), Foley's group had the highest mean IDI (  $14.56 \pm 2.92$  hr) where as Primiprost group had the lowest mean IDI (  $10.72 \pm 5.48$  hr ) & Cerviprime group had in between the two (  $13.67 \pm 8.69$  ) .

On analysis though no statistical differences in Foetal outcome in the study groups was made, NICU admission was maximum in Primiprost group (11.11 %) in comparison to Cerviprime group (5.55%) & Foley's group (3.84%).

# **CONCLUSION**

The ideal priming agent is one that causes cervical changes i.e. most similar to that seen in natural ripening process. Such an agent would not cause contractions and in no way affect uterine blood flow or the foeto- placental unit. Many of foetuses involved in these induction are at high risk and especially susceptible to having late and variable deceleration. Indeed fetal demise during the ripening process has been reported when laminaria was used and in two cases when extra amniotic PGE2 was used. Thus the presence of uterine activity would require continuous fetal monitoring ,even during the pre induction ripening process if the foetus is at risk.

Inflated Foley's catheter for priming of an unfavorable cervix is of proved value but the role in inducing uterine contractility is poor. Prostaglandins are very good inducers of labour but they are not free from side effects like failed induction and foetal jeopardy. Cervical ripening with extra amniotic balloon catheter possesses the advantages of simplicity, low cost, reversibility & lack of severe side effects & so seems to be an ideal method for acceptance where prostaglandins are contraindicated or when uterine hyperstimulation should be avoided such as in cases of intra uterine fetal growth retardation, placental insufficiency, asthmatic patients, diabetics and so on.

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