

Comparative Study of Intra-Cervical Foley's Catheter and Intra-Cervical PGE₂ Gel For Pre-Induction Ripening of Cervix

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ABSTRACT

Introduction: Numerous techniques have been used to ripen the unfavourable cervix to achieve the changes necessary for labour. Prostaglandins are the most commonly used pharmacological agents for ripening of cervix and PGE₂ gel is the agent of choice for this purpose.

Materials and methods: In present study 100 singleton pregnant women who were counselled & in whom cervical ripening and labour induction was indicated were studied. 50 women received Foley's catheter intra-cervically and bulb inflated with 30ml of normal saline & the remaining 50 women received 0.5mg of Dinoprostone gel.

Results: Majority of patients in Foley's group had bishops score 2 in 48% & 50% in dinoprostone forming a major group. The mean induction delivery interval was 13.9 hrs & 11.5 hrs in primigravidae & multigravidae respectively, giving a total mean of 12.5 hrs. 82% had vaginal delivery & 18% had caesarean delivery in Foley's group as compared to dinoprostone where vaginal delivery was 68% & caesarean delivery 36%. The rate of failed induction was 22% in Foley's group, the major indication being fetal distress & secondary arrest of dilatation. In dinoprostone group 36% cases were failed induction, major cause was secondary arrest of dilatation. There was 10% incidence of side effects of dinoprostone of which 2% hyper stimulation, 2% fever, 2% vomiting, 2% diarrhoea, 2% PPH. In Foley's group the incidence of side effect is 2% vomiting. There was 4% incidence of NICU admission in Foley's group & 12% in dinoprostone group.

Conclusion: Study suggest that Foley's catheter & PGE₂ gel are showing almost equal results, but Foley's catheter is a safer, easier, cheaper, effective method of pre-induction cervical ripening and can be used in PGE₂ contraindicated cases.

Key words: Foley's catheter, Dinoprostone, Cervical ripening.

called pre-labour which takes four to five weeks and starts around 35 weeks of gestation and culminates with clinical labour at term. The critical events in pre-labour are myometrial excitement and cervical ripening. The success of induction depends on the degree of these pre-labour changes. But when the fetus is compromised or when continuation of pregnancy may harm the mother or fetus we cannot wait until nature brings about cervical ripening. The unripe cervix impedes attempts and predisposes patients to increased fetal and maternal morbidity.

There is little doubt that cervical ripening facilitates labour and ultimately influences the process of vaginal delivery.^{3,4} Induction of labour when cervix is unripe is associated with maternal complications and high rates of induction failure.⁵ Variety of cervical scoring systems are described but Bishops pelvic score is most commonly used for cervical assessment prior to induction.⁶ Cervix is considered unfavourable if the derived score is <6 and cervical ripening is indicated prior to artificial rupture of membranes and oxytocin to reduce the incidence of failed induction and caesarean delivery.⁷

Several factors seem to play a role in the ability to successfully induce labour. One of the most important factor appears to be the cervix i.e., defined as favourable for vaginal delivery. Bishop⁸ first described the correlation between the presence of favourable cervix and subsequent vaginal delivery. Successful outcome of induction relies on cervical favourability. So there comes the need for improving cervical score in those women with unfavourable cervix for success of induction of labour and subsequent vaginal delivery. This process has been described as pre-induction cervical ripening. Numerous techniques have been used to ripen the unfavourable cervix to achieve the changes necessary for labour.^{9,10} Presently pharmacological and mechanical agents are used to modify the cervical status. Prostaglandins are the most commonly used pharmacological agents for ripening of cervix and PGE₂ gel is the agent of choice for this purpose¹¹, but expensive.¹²

A variety of more economical mechanical methods are also

INTRODUCTION

One of the most important tools in an obstetrician armamentarium is the capacity to deliver a patient when required. This is possible by induction of labour or by caesarean section. Labour induction is an artificial initiation of labour prior to its spontaneous onset for the purpose of accomplishing delivery of feto-placental unit.¹ The aim of induction of labour is to achieve vaginal delivery in advance of the normal timing parturition without subjecting the mother or fetus to under risk. Induction of labour is often essential when obstetric or medical problems affect the fetal or maternal well being. In view of this, the method of induction has to be both safe and effective. It is indicated where the benefits to mother/fetus outweigh the benefits of continuing pregnancy.² The transition from pregnancy to labour is a gradual process

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used for cervical ripening like intra cervical Foley's catheter, bougie and hygroscopic laminaria tents. The use of Foley's catheter for cervical ripening was first described by EMBREY and MOLLISON in 1967.¹³ There after various balloon catheters have been used to induce cervical ripening¹⁴

The human cervix is an organ of diverse properties. Ripening of cervix takes place during pre-labour phase, resulting in increased softening, effacement, distensibility and early dilatation. Pre induction cervical ripening can be divided into pharmacological and mechanical methods. One of the most common pharmacological methods of cervical ripening is the use of a Prostaglandin E₂ gel. Use of Foley's catheter for the induction of labour was first described by KRAUSE IN 1853.¹⁵ In 1967 Embrey and Mollison reported a 94% successful induction rate after using Foley's catheter for cervical ripening. The Foley's catheter appears to effect the cervical ripening not only through direct mechanical dilatation of cervix but through release of prostaglandins.

The release seem to be increased by further separation of amnion from the decidua.¹⁶ This led many investigators to instil fluid through an in place Foley's Catheter provides a possible increase in success of pre induction cervical ripening. The aim of this study is to compare the efficacy of intra cervical Foley's catheter and intra cervical PGE₂ gel for pre induction ripening of cervix. Termination of pregnancy by inducing labour is often indicated in obstetrics patients, when continuation of pregnancy may harm the mother or fetus.

MATERIALS AND METHODS

This is conducted in Department of obstetrics and gynaecology at the Government Maternity Hospital, Hanamkonda, attached to Kakatiya Medical college, Warangal, Study period starts from December 2011. The study group consisted of 100 antenatal women admitted in the hospital for the safe institutional delivery who required pre-induction cervical ripening.

Labour was induced in fifty women with Foley's catheter

and remaining fifty women with similar inclusion criteria with 0.5gm Dinoprostone gel and thus efficacy of both methods is compared.

Inclusion Criteria: Gestational age ≥ 37 weeks, Singleton pregnancy, Cephalic presentation, Parity less than 4, Reassuring fetal status and Bishop's score ≤ 6

Exclusion Criteria: Twin pregnancy, Parity more than 4, Malpresentations, Ruptured membranes, APH, Polyhydramnios, Previous LSCS and Medical disease complicating pregnancy

Patients at term with various indications for induction of labour will be included in the study after a written and valid consent. Patients are admitted and will be evaluated by a proforma which includes history, physical examination, obstetric examination, ultrasound and Doppler study of the fetus.

The patients will be divided into two groups,

Group A intracervical Foley's catheter insertion size no:16 with 30ml of normal saline and

Group B intra cervical PGE₂ gel administration will be done.

The pre and post induction cervical ripening will be compared between two groups. The induction delivery interval, maternal and fetal out come and need for augmentation of labour also will be compared.

RESULTS

Total number of patients studied was 100. Fifty patients were induced with Foley's catheter and bulb inflated with 30ml of normal saline and the remaining 50 patients were induced with 0.5mg of PG E₂ gel intracervically.

From the Table 1 it can be seen that in the Foley's group out of 50 patients, 34 were booked and 16 were unbooked, giving an incidence of 68 and 32% respectively. In the dinoprostone group, out of 50 patients, 35 were booked and 15 were unbooked, giving an incidence of 70% and 30% respectively. Parity was compared in both groups. Found to be similar with no statistical difference. Primi gravidae form the largest group in the study being 80% and 88% in Foley's and Dinoprostone respectively.

	Foley's		Dinoprostone	
	No. of patients	%	No. of patients	%
Booked	34	68%	35	70%
Unbooked	16	32%	15	30%
Parity				
Primi	40	80%	44	88%
Multi	10	20%	06	12%

Table-1: Booking and Parity

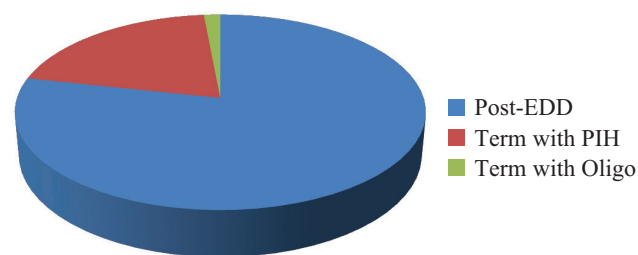


Figure-1: Indications for induction

Bishop's score		1 to 3		4 to 6		7 to 10	
		No. of patients	%	No. of patients	%	No. of patients	%
Foley's	Primi	1	02%	30	60%	09	18%
	Multi	2	04%	04	08%	04	08%
Dino-Prostone	Primi	10	20%	32	64%	02	04%
	Multi	02	04%	02	04%	02	04%

χ^2 equals to 10.165 with 2 degrees of freedom the p value equals to 0.0062 the association is considered to be statistically significant.

Table-2: Modified Bishops score after induction

Drug	Parity	Idi (hrs)	Term-pih	Post edd	Term-oligo	Hrs	Mean hrs
Foley's	Primi	<6hrs	-	-	-	11.8	10.2
		6 to12hrs	2	15	-		
		12to18hrs	4	17	2		
		18to24hrs	-	-	-		
	Multi	<6hrs	1	1	-	8.6	
		6to12hrs	2	5	1		
		12to18hrs	-	-	-		
		18to24hrs	-	-	-		
Dino-Pro-Stone	Primi	<6hrs	1	1	-	13.9	12.7
		6-11 hrs	1	3	1		
		12-18 hrs	6	23	1		
		18-24 hrs	2	4	1		
	Multi	<6hrs	-	-	-	11.5	
		6-11 hrs	-	2	1		
		12-18 hrs	-	2	1		
		18-24 hrs	-	-	-		

Table-3: Induction to delivery interval

Indication	Foley's	Dinopros-tone
Fetal distress		
Meconium stained Liquor	6	7
Bradycardia due to hyper stimulation	0	1
Failure to progress		
Deep transverse arrest	0	0
Secondary arrest of dilatation	5	10
Complications		
Tachysystole	0	0
Hyper stimulation	0	1
Fever	0	1
Vomiting	1	1
Diarrhoea	0	1
Post partum haemorrhage	-	-
Atonic	0	1
Traumatic	0	0
No. of NICU admissions	4	12

Table-4: Failed induction

The various indications for induction were term with PIH, Post EDD, Oligo with AFI-6. Post EDD formed largest group for induction in both groups.

In Foley's group majority of primi gravidae delivered within 12-18 hrs. In multigravidae majority is between 6-12 hrs indicating more effective in multies. In Dinoprostone group majority of primi gravidae delivered between 12-18 hrs, In multigravidae equally in 6-12 hrs and 12-18 hrs. χ^2 equals to 17.54 with 3 degrees of freedom the p value equals to 0.00054 the association is considered to be statistically significant

Thus in induction delivery interval in Foley's group among primi was 11.8 hrs and in multi is 8.6 hrs and giving a total mean of 10.2 hrs The mean induction delivery interval in dinoprostone group among primi is 13.9 hrs and in multi is 11.5 hrs giving a total mean of 12.7 hrs.

In this study caesarean section in Foley's was 18% and Dinoprostone was 32%

The rate of Failed induction was 22% in Foley's group and 36% in dinoprostone group. In Foley's the indication were Fetal distress and secondary arrest of dilatation with 12% and 10% each. In dinoprostone group the indications were Fetal distress 16% and secondary arrest of dilatation 20%. There are 2% incidence of side effects in Foley's group and 10% incidence of side effects in dinoprostone group. In Foley's group 4 admissions were made since Meconium stained liquor was observed. In Dinoprostone group 12 cases were admitted in NICU

DISCUSSION

The secret of induction of labour lie in replicating as closely as possible, the process of spontaneous parturition. Ideally a cervical ripening cervical remodelling without stimulating Uterine activity. It should be effective, convenient, safe and inexpensive. Most common indication for induction was post dated pregnancy and PIH.^{17,18,19} Cervical ripening is a normal prelude to onset of Myometrial contraction, it is important to choose a method which will ripen the cervix and have a successful outcome of planned induction of labour.

In our study both Foley's and Dinoprostone have been equally effective in achieving cervical ripening and improving Bishops score and promoting changes resembling physiological events of ripening and labour. In today's expensive world, Foley's catheter which is half the price of Dinoprostone gel is definitely a safer and cheaper alternative. The use of Foley's catheter to effect cervical ripening was first described by Embrey Mollison in.²⁰

The mechanical action of Foley's balloon strips the fetal membranes from the LUS and start the process of prostaglandin release which increase the consistency and effacement of cervix. The advantage of such mechanical methods of induction are simplicity of its use, potential for reversibility, reduction in certain side effects like excessive uterine activity and low cost.²¹

Foley's catheter can also be used in case of Bronchial asthma, increased intraocular pressure, post-LSCS, thus Foley's

catheter provides better alternative. In our study of 100 cases, we have analysed mean duration of labour, maternal and fetal outcome. Main argument against Foley's catheter has been risk of introduction of infection with accidental rupture of membranes.

In our study, no such accidental rupture has occurred. Foley's catheter acts as a mechanical dilator and improves dilatation rather than effacement of cervix, whereas Dinoprostone gel acts by softening and increases effacement of cervix, rather than dilatation. For successful Foley's catheter induction, immediate Amniotomy followed by oxytocin drip is needed as a cervix tends to close down after removal of Foley's.

Prostaglandin in general especially PGE₂ are extensively used for cervical ripening. They reduce the likelihood of not being delivered in 24hrs and decrease the use of oxytocin for augmentation but with higher rate of uterine hyper stimulation.²² Dinoprostone gel is expensive, twice as much as price of Foley's, also it has to be stored in refrigerator at 6-8°C as in our study the side effects of Dinoprostone gel like nausea, vomiting, diarrhoea are quite frequent, whereas they were absent in Foley's.

Cases of uterine hypertonicity and fetal bradycardia have been reported following use of prostaglandins and this necessitated monitoring of fetus even in pre-induction cervical ripening procedure, when these potent agents are used, as compared to Foley's where no such specific monitoring was required. Multiple studies have been done comparing effectiveness and safety between prostaglandins and Foley's catheter.

Sciscione et al.,²³ compared the two methods and showed that Foley's group had shorter induction delivery interval. St. Onge and Connors²⁴ found that both Foley's catheter and PGE₂ gel methods led to similar improvement in bishops score.

In the present study, 100 patients were studied with indications for induction of labour. These patients had poor bishops score. So pre-induction cervical ripening was done in these 100 patients, of whom 50 patients received Foley's induction extra-amniotically with bulb inflated with 30ml of normal saline and remaining 50 patients received intra cervical dinoprostone gel (0.5mg).

Induction delivery interval was significantly shorter in Foley's catheter group. Similar results were obtained by Niromanesh et al.,²⁵ and Orhue et al.,²⁶ and our present study support these results. Ghezzi et al., compared extra amniotic Foley's and PGE₂ gel for cervical ripening at term and concluded that Foley's catheter is a valid alternative to the application of intravaginal PGE₂ gel.²⁷

James et al., also confirmed that Foley's catheter is not associated with any complications.²⁸ In majority of patients in Foley's group and dinoprostone group were booked cases. The rate of vaginal delivery was 82% in Foley's group and 68% in dinoprostone group. Studies showing vaginal delivery rate in Foley's group are; St. Onge R D, Connors G T 70.6%, Sciscion A C, MC Collough²³ 73%, Ezimokhai and Nwabinelli JN²⁹ 85%. Studies showing vaginal delivery rate in Dinoprostone group are; St. Onge R D, Connors G T²⁴

70.4%, Sciscion A C, MC Collough²³ 71%, Ezimokhai and Nwabinelli JN²⁹ 57%.

In present study, the rate of vaginal delivery in Foley's group is consistent with Ezimokhai and Nwabinelli²⁹. The vaginal delivery rate in dinoprostone group in present study is consistent with St. Onge R D, Connors G T²⁴ and MC Collough.²³ In present study it was shown that mean modified bishops score after >6hrs was more in Foley's group as compared to dinoprostone group. The mean bishops score in Foley's group was 5.8 % in dinoprostone group was 4.8%, which is consistent with Sciscion AC, MC Collough²³ who observed mean bishop score after >6hrs was 6.5 and 5.1 in Foley's and dinoprostone group respectively.

In the present study it was seen that induction delivery interval was shown in Foley's group compared to dinoprostone group- 10.2 hrs and 12.7 hrs respectively which is statistically significant. Studies showing induction delivery interval in Foley's group and dinoprostone group are St. Onge R D, Connors G T²⁴ 16±1.7 hrs and 21.5±3.2 hrs; Ezimokhai and Nwabinelli et al.²⁹ 9.2±2.7 and 10.6±2.5 hrs respectively. James C, peedicayil et al²⁸ showed 8.7 hrs in Foley's group. Y. Onekura et al. showed 13.1±8.1 hrs in dinoprostone.

Present study showed that Foley's catheter had induction delivery interval is less than dinoprostone and is consistent with Ezimokhai Nwabinelli et al.²⁹ Failed induction were those cases which did not fulfil the criteria for the definition of induction of labour. Thus all caesarean deliveries were considered failed induction, irrespective of cause of the same.

Caesarean delivery rate in a study was 18% and 32% in Foley's and dinoprostone group respectively. The various indications were fetal distress and failure to progress. In Foley's group both indications were almost same but in dinoprostone group failure to progress is major. Present study caesarean section rate is consistent with St. Onge and connors²⁴ study in Foley's group and Dinoprostone group with Ezimokhai Nwabinelli.²⁹

The maternal side effects observed were Tachysystole, Hyper-stimulation, Vomiting, Diarrhoea, PPH. Cases of uterine Hyper stimulation and fetal bradycardia have been reported following use of prostaglandin and strict FHR monitoring in pre induction period is required as compared to Foley's catheter where no specific monitoring is required.

In present study no such complications noted in Foley's group but in dinoprostone group 2% was observed. In Foley's group present study showed 2% vomiting, but not significant. There was no infection. Foley's as when used ripe cervix prior to surgical induction of labour. The main argument against its use was risk of infection. Study showed no risk of infection. In dinoprostone group other complications were fever, diarrhoea, PPH. Other parameters like gestational age, parity, indications for induction, FHR and neonatal outcome have no difference in both the groups.

CONCLUSION

Foley's catheter is safe and effective method of cervical ripening before induction of labour as dinoprostone and much more cost effective as compared to dinproston. Foley's cath-

eter is not complicated by fetal heart rate pattern abnormalities as compared to dinoprostone. So strict FHR monitoring is not required in pre-induction period. Incidence of infection, though expected in high is not found to be increased in the present study. Risk of preterm labour in subsequent pregnancy was proved to be absent by several studies with Foley's induction.

So the results of this study suggest that Foley's catheter and PGE₂ gel are showing almost equal results, but Foley's catheter is a safer, easier, cheaper, effective method of pre-induction cervical ripening and can be used in PGE₂ contraindicated cases.

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