



COMPARATIVE STUDY OF PREINDUCTION CERVICAL RIPENING AT TERM GESTATION WITH FOLEY CATHETER AND PGE2 GEL INTRACERVICALLY.

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ABSTRACT To know the efficacy of mechanical separation of membranes with Foley catheter and efficacy of PGE2 gel in cervical ripening.
Comparison of the efficacy of the above two procedures.

KEYWORDS :cervical ripening, Bishop score Foley catheter, PGE2 gel, NST.

Introduction

This study was conducted in department of Obstetrics and Gynaecology, Government General Hospital, Kurnool from 2016 – 2017 at Kurnool, A.P. South India.

The goal of obstetrics is a pregnancy that results in a healthy infant and a minimally traumatised mother. To achieve this goal, an ideal method for induction of labour should have efficacy and safety for both mother and fetus. The success of induced labour depends on the degree of ripening of the cervix, which can be best assessed objectively by inducibility score as developed by bishop.

Cervical ripening refers to prelabour phase where cervical changes occurs in consistency, position, effacement and dilatation where as induction refers primarily to attempt to produce regular uterine contraction along with cervical changes to begin the active stage of labour.

Induction can be defined as an intervention intended to artificially initiate uterine contractions resulting in the progressive effacement and dilatation of the cervix.

Calder et al (1964) has shown that there is an increase in duration of labour, maternal pyrexia, caesarean section and birth asphyxia in patients who were induced by oxytocin infusion and amniotomy with unprepared cervix as compared with who underwent cervical ripening before induction of labour. Unfavourable cervix is associated with high chances of unsuccessful induction.

Nowadays, incidence of induction of labour has increased because of increased incidence of pregnancy induced hypertension, prolonged pregnancy etc. although systemic or local application of proinduction agents like oxytocin and prostaglandins have gained widespread use in recent years, mechanical methods for cervical ripening are less popular. The use of extra amniotic catheter balloon inflated above the internal cervical os has been advocated as a safe, low-cost, and non-pharmacological method of cervical ripening before induction of labour. In this institute, foley's catheter is being used for mid-trimester abortion but not for cervical ripening before induction of labor for the fear of introducing infection.

The present study was carried out to test and compare the efficacy and safety of extra amniotic foley's catheter balloon with that of intracervical prostaglandin E2 gel for cervical ripening.

The study was conducted on 100 pregnant women attending the labour ward for induction of labour.

Inclusion criteria :

1. Singleton term pregnancy with cephalic presentation.
2. Intact membranes.
3. Bishop score less than 5

4. Reactive NST.

Exclusion criteria :

1. Cephalopelvic disproportion
2. Non reactive NST
3. Previous uterine scar, placenta previa
4. Hypersensitivity to prostaglandins.
5. Parity > 5.

Out of 100 women, 50 were randomized to Group – A Foley catheter group and rest of 50 to Group – B gel group. After meeting the inclusion and exclusion criteria and informed and written consent is taken.

Outcome

The outcome of the study was compared between the two groups in terms of the following parameter.

Bishop score before and after 12 hours of insertion of Foley's catheter and prostaglandin gel Oxytocin augmentation required or not.

Interval between intervention and onset of labour.

Mode of delivery (spontaneous, operative vaginal, caesarean section).

Indication for caesarean section
Induction-delivery interval time.
Side effects and complication.

Neonatal outcome was compared in terms of perinatal morbidity and mortality.

Observations and results.

Age wise distribution on both groups:

Majority of pregnant women are in 21-25 age in both the groups.

Antenatal care registration:

Booked cases are 40% in foley group and 34% in PGE2 group.
Unbooked cases are 60% in Foley group and 66% in PGE2 group.

Distribution of women according to parity:

Nulliparous women are 30% in Foley group and 68% in PGE2 group.
Multiparous women are 40% in Foley group and 32% in PGE2 group.

Gestational age:

In terms of gestational age

Between 37-38 weeks foley group : 11 cases (22%), PGE2 gel group : 8 cases (16%).

Between 39-40 weeks Foley group : 16 cases (32%),
PGE2 gel group : 13 cases (26%).

Between 41-42 weeks Foley group : 23 cases (46%),
PGE2 gel group : 29 cases (58%).

Indication :

Sl no	Indication	Foley		PGE2	
		No of cases (50)	%	No of cases (50)	%
1	Prolonged pregnancy	25	50	20	40%
2	PIH	8	16%	12	24%
3	Mild-moderate oligo	12	24%	12	24%
4	Rh -ve pregnancy	3	6%	4	8%
5	IUGR	2	4%	2	4%

In the present study most common indication for induction of labour was prolonged pregnancy followed by pregnancy induced hypertension and mild to moderate oligohydramnios.

Preinduction Bishop Score

In this study pregnant women having bishop score less than 5 were considered. Initial mean Bishop score was 3.02 in Foley group and 3.08 in PGE2 Gel group.

There is no significant difference between these groups.

Post induction Bishop score with Foley catheter at 12 hours. After 12 hours out of 50, 2 cases were with Bishop score less than 5. 47 patients were with Bishop score more than 6 and among them 5 cases delivered spontaneously.

Post induction Bishop Score with PGE2 gel. After 12 hours out of 50, 19 cases with Bishop score less than 5 were repeated with PGE2 gel.

After 12 hours out of 50, 5 cases delivered spontaneously and 26 cases were with Bishop score more than 6.

Comparison of post induction Bishop score in both groups at 12 hours.

PostInduction Score	Foley		PGE2	
	No of cases (50)	%	No of cases (50)	%
4	1	2.17%	3	6.52%
5	1	2.17%	16	34.79%
6	15	32.61	6	13.04%
7	16	34.79%	6	13.04%
8	6	13.05%	8	17.34%
9	5	10.87%	4	8.69%
10	2	4.34%	3	6.52%

Out of 50 in 2 cases Foley catheter expelled spontaneously at 10 hours and 11 hours respectively, 2 cases had PROM.

Out of 50 in PGE2 gel group 3 cases had PROM, 1 case had hypertonic contraction.

Bishop score at 0 and 12 hr and the difference between two observations.

There is no significant difference in initial Bishop Score between both groups. After 12 hours mean bishop score in foley group is 6.82 compared with PGE2 gel is 6.52 respectively.

Additional applications required for PGE2 gel group.

Out of 50 cases 31 cases had favourable response with first application and 19 cases needed second application.

Mode of delivery in both groups.

Sl no	Mode of delivery	Foley		PGE2	
		No of cases (50)	%	No of cases (50)	%
1	Vaginal delivery	37	74	29	58
2	Forceps delivery	6	12	8	16
3	ventose	-	-	-	-
4	Caesarean section	7	14	13	26

In Foley group 54% of cases had vaginal delivery, 12 % of cases had outlet forceps delivery, and 14 % of cases had caesarean section. In PGE2 58% of cases had vaginal delivery, 16% of cases had Forceps delivery, 26% of cases had caesarean section.

Indications for forceps delivery:

In Foleys group delivery was done for 3 cases to cut short II stage labour, failed maternal forces for 2 cases, and fetal distress in 1 case. In PGE2 group delivery was done for 3 cases for failed maternal forces, 3 cases for fetal distress, 2 cases to cut short II stage of labour.

Indications for caesarean section :

In foley group caesarean section was done for fetal distress in 2 out of 8 cases compared to 5 out of 13 cases in PGE2 gel group. Fetal distress and failed induction were indications for caesarean section which were more in PGE2 gel group compared to Foley group.

Number of patients who require oxytocin :

In Foley group 42 cases required oxytocin for further augmentation compared to 30 cases in PGE2 gel group.

Induction delivery interval:

Sl no	hours	Foley		PGE2	
		No of cases(50)	%	No of cases(50)	%
1	12	2	4	3	6
2	12-24	34	68	31	48
3	>24	14	28	16	46
4	total	50	100	50	100

Maximum number of cases delivered in 12-24 hours in foley group and after 24hours in PGE2 group.

Intrapartum complications:

Out of 50cases 2 cases in foley group and 3 cases in PGE2 group had PROM.

Out of 50 cases, 3 cases in foley group and 8 cases in PGE2 group had fetal distress.

One case in PGE2 had hypertonic contraction. None of the cases in both groups had maternal pyrexia.

Postpartum complications:

Out of 50 cases, 3 cases had pph in PGE2 group and none in Foley group.

Side effects:

Out of 50 cases one case had PROM, 1 case had discomfort in foley group.

Out of 50 cases 7 cases had vomiting, 1 case had hypertonic contractions, 3 cases had bleeding and 3 cases had PROM in PGE2 gel group.

Comparison of APGAR score in both groups:

Out of 50 cases 3 cases in foley group and 8 cases in PGE2 group had fetal distress.

Summary and conclusion

The present study was designed to compare the efficacy of Foley catheter with PGE2 gel in preinduction cervical ripening at term gestation.

The study was carried out at Government general Hospital, Kurnool on 100 antenatal cases, 50 patient in each group both primigravidae and multigravidae who were at term gestation.

The age group, parity and the period of gestational age were compared in both groups. There is no significant difference between both groups.

The majority of indications for induction of labour were prolonged pregnancy folloed by pregnancy induced hypertension and mild to moderate oligohydramnios.

In foley group the mean initial bishop score was 3.02. After 12 hours the mean Bishop score was 6.82. In PGE2 gel group the mean initial Bishop score was 3.08. after 12

hours the mean Bishop score was 6.52.

Mean improvement in Bishop score is 3.8 ± 1.2 and 3.44 ± 1.0 in foley group and PGE2 gel group respectively.

The mean improvement in both group is almost equal.

In foley group almost all cases had favourable response. But in PGE2 gel group, out of 50 cases 31 cases had favourable response with first application. 19 cases needed second application. ($\chi^2=18.86$, P.value < 0.05 which is statistically significant).

The mean induction delivery interval 21 ± 7.3 hours, 24 ± 9.4 hours in Foley group and PGE2 gel group respectively.

In foley group 86% of cases had vaginal delivery, 14% of cases had caesarean section.

In PGE2 gel group 74% of cases had vaginal delivery, 26% of cases had caesarean section.

In Foley group, caesarean section was done for fetal distress in 2 out of 8 cases compared to 5 out of 13 cases in PGE2 gel group.

Fetal distress and failed induction were indications for caesarean section which were more in PGE2 gel group compared to foley group.

Minimal side effects in foley group. But PGE2 gel group 7 cases had vomiting, 3 cases had PROM, 3 had PPH, 1 case had hypertonic contraction.

Conclusions:

It can be concluded that cervical ripening with extra amniotic foley's catheter balloon has the advantages of simplicity, low cost, reversibility and absence of systemic or serious side effects. It brings about cervical ripening with favourable bishop score and repetition of procedure is not required.

Overall the method is safe, cheaper and effective alternative to PGE2 gel and particularly suitable for Indian setup.