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A Comparative Analysis of Safety and Efficacy of Foley's Catheter and PGE 2 Gel For Cervical Ripening And Induction of Labour-RCT

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Introduction

Induction of labour is the artificial initiation of labour prior to its spontaneous onset for the purpose of accomplishing delivery of feto-placental unit[1]. Cervical ripening is a process of preparing the cervix by cervical effacement and dilatation (as measured by Bishop's score) for labour induction [2].It is indicated where the benefit to either the mother or the foetus outweighs the benefits of continuing pregnancy[3].

Induction of labour should be simple, safe, effective and preferably non-invasive. The success of induction depends to a large extent on the consistency, compliance and configuration of the cervix[4]. Bishop's pelvic scoring system is most commonly used for cervical assessment prior to induction[5]. Cervix is considered unfavourable if the score is less than 6 and cervical ripening is indicated prior to artificial rupture of membranes and oxytocin infusion to reduce the incidence of failed induction and caesarean delivery[6].With low Bishop's score, there may be increased rate of caesarean section delivery, maternal fever and fetal hypoxia [7,8].

Numerous techniques have been used to ripen the unfavorable cervix to achieve the changes necessary for labour [9,10]. Presently pharmacological and mechanical agents are used to modify the cervical status [1].

Prostaglandins are most commonly used pharmacological agents for ripening of cervix and PGE2 is the agent of choice for this purpose [11]. Prostaglandins are derivatives of prostanoic acid and act as local hormones. They have direct effect on the production of procollagenases which is precursor of collagenase, decreases collagen and increases hyaluronic acid which in turns soften the cervix and helps in cervical effacement and dilatation.

The use of Foley's Catheter to effect cervical ripening was first described by Embrey and Mollison in 1967[12]. Thereafter various balloon catheters have been used to

induce cervical ripening[13]. Intracervical Foley's catheter induction produces a mechanical distension of the lower uterine segment. It can cause mechanical dilatation of cervix and stimulates endogenous release of prostaglandins by stripping the fetal membranes and release of lysosomes from decidual cells [14,15].

This study was planned to compare the efficacy and safety of 50 ml. intracervical Foley's catheter balloon with that of Dinoprostone gel for cervical ripening before induction of labour at term.

Aim: To determine safety and efficacy of Foley's catheter and PGE2 gel for induction of labour.

Primary Objectives: To compare safety and efficacy of Foley's catheter with PGE2 gel.

Secondary Objectives

1. Demographic Profile of both groups.
2. Mean changes in the Bishop score in both groups.
3. Mode of delivery, Induction and delivery interval time in both groups.
4. To study the rate of infection in both groups.
5. To compare and analyse obstetric and perinatal outcome in both groups.

Material and Methods

- **Study Design**: Randomised Controlled Trial, Prospective Study.
- **Study Area**: Department of Obstetrics and Gynaecology, GMERS Medical college, Junagadh.
- **Study Period**: August 2021 to August 2022
- **Study Population:** All women with indication for induction of labour as per inclusion criteria in labour room of GMERS Medical college, Junagadh

Sample Size: 200

- In group of Cerviprime gel-100
- In group of Foley's catheter-100

Randomisation Technique: Computer generated table of random numbers.

Statistical Method Analysis

1. Quantitative variables were compared using independent t test/Mann- Whitney Test.
2. Qualitative variables were compared using Chi-Square test/Fisher's Exact test.

A p value of <0.05 was considered statistically significant.

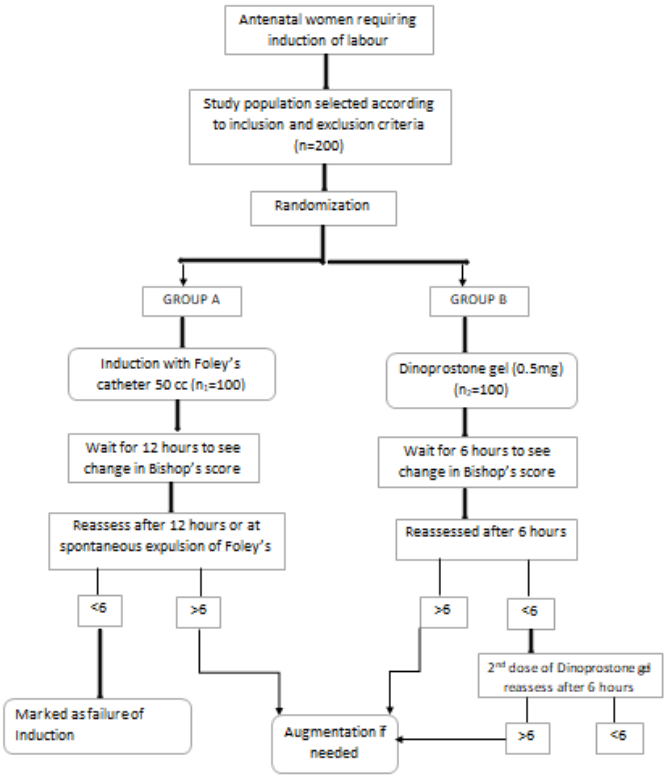
Inclusion criteria

- ≥28 weeks of gestation
- Bishop's score ≤ 3
- Singleton pregnancy
- Cephalic presentation
- Intact membranes

Exclusion criteria

- Contracted Pelvis
- Scarred uterus
- Pre-existing Maternal medical disorders like heart disease, renal disease
- Placenta previa
- Multiple pregnancy
- APH

Dose repetition of PGE2 gel was considered if post induction Bishop's score become ≤6 in both the groups. Need of augmentation of labour was assessed and implemented by other methods such as artificial rupture of membrane (ARM) and/or oxytocin administration. Failure of induction was declared if patient failed to go in active phase of labor within 48 hours of induction.



Foley's catheter

An 18 size Foley's catheter (it comes in pre-sterilized pack using ethylene oxide) was introduced through cervix to extra-amniotic space using a sterile technique with the aid of a speculum and sponge holding forceps and 30 ml distilled water was instilled into the balloon. Then balloon is pulled up to the internal os. Catheter was tapped with thigh. Prophylactic antibiotic was given.

Prostaglandin gel

PGE2 gel is available in the name of cerviprime gel as a sterile preparation containing 0.5 mg of dinoprostone per 3 gm (2.5 ml) of gel in a prefilled syringe with a catheter for endocervical application. After exposing the cervix by speculum 0.5 mg of PGE2 was inserted intra cervically from a loaded syringe and the patients were kept in lying down position at least 30 minutes for absorption of drugs.

Results

Table 1: Demographic Profile

Variable	Group A	Group B	P value
Mean Age	25.68 ± 3.84	25.68 ± 3.84	0.399
Mean Gestational Age	39.61 ± 1.54	39.52 ± 1.3	0.427
Parity			
Nullipara	52 (52.00%)	58 (58.00%)	0.394
Multipara	48 (48.00%)	42 (42.00%)	
Indication For Induction			
Post Date	45(45%)	38(38%)	0.144
Oligohydroamnios	26(26%)	32(32%)	
Severe Preeclampsia	15(15%)	24(24%)	
Eclampsia	13(13%)	5(5%)	

Table 2: Mode of Delivery and Induction To Delivery Interval In Both Groups

Mode of Delivery	Group A	Group B	P value
Vaginal	76(76.00%)	79(79.00%)	0.720
Instrumental	2(2.00%)	3(3.00%)	
LSCS	22(22.00%)	18(18.00%)	
Induction To Delivery Interval			
	13.1±3.05	13.58±2.51	0.149

Table 3: Comparison of Bishop's Score between Two Groups

Bishop's Score	Group A	Group B	P Value
Mean Pre-Induction Score	2.09±0.53	2.06±0.64	0.71
Mean Post Induction Score	8.92±1.67	8.41±1.80	0.39
Mean Change	6.66±1.59	6.08±1.59	0.11

Table 4: Need for Augmentation in Both Groups

Method of Augmentation	Group A	Group B	P Value
Arm	16(17.97%)	12(13.79%)	0.55
Arm + Oxytocin	21(23.59%)	26(29.88%)	
Oxytocin	52(58.42%)	49(56.32%)	
Requirement of Augmentation			
Yes	11.00 %	13.00%	
No	89.00 %	87.00 %	

Table 5: Indication for LSCS In Both Groups

Indication For LSCS	Group A	Group B	P Value
Fetal Distress	9(40.90%)	6(33.33%)	0.88
Meconium Stained Liquor	7(31.81%)	5(27.77%)	
Failure Of Induction	5(22.72%)	6(33.33%)	
Non Profress Of Labour	1(4.54%)	1(5.55%)	

Table 6: Neonatal Outcome

Variable	Group A	Group B	P Value
NICU Admission			
Yes	13(18%)	12(12%)	0.83
No	87(88%)	88(88%)	
Indication of NICU Admission			
Mas	3(3%)	3(3%)	0.91
Asphyxia	10(10%)	9(9%)	
Apgar Score At 1 Min <7	11(11%)	10(10%)	0.096
Apgar Score At 5 Min <7	6(6%)	5(5%)	0.097
Mean Birth Weight	2.65±0.25	2.65±0.28	0.572

Both the groups were comparable with respect to the maternal age, gestational age, indication for induction and pre-induction Bishop's score. No statistically significant difference was demonstrated between the two groups.

Table 1 shows that the mean age of the patients in the study was 25.68±3.84 years in Group A and 25.33±3.91 years in Group B (p value 0.39). Mean gestational age was 39.61±1.54 weeks in group A and 39.52±1.3 weeks in group B (p value 0.42). Parity wise both groups **were comparable** and result was statistically non-significant (p value= 0.394). Both groups were **comparable** for indication of induction with p value 0.144.

Table 2 shows no significant statistical difference in spontaneous vaginal delivery in both the groups. The need for operative intervention (LSCS) was also not significant in both the groups. There were 76(76%) and 79(79%) spontaneous vaginal delivery in group A and group B respectively. There were 2(2%) and 3(3%) instrumental deliveries in group A and group B respectively. In group A the LSCS rate was 22% as compared togroup B (18%) which was slightly higher than group B . It also shows induction to delivery interval in both groups.In group A it was 13.1±3.05 hours compared to group B 13.58±2.51 hours. (p value 0.149)

Table 3 shows mean change in bishops score in both groups after induction. This table summarize bishops at 0 hours and at spontaneous expulsion of Foleys/at 12 hours or at 6 hours/12 hours in cerviprim group.In group A mean preinduction bishops was 2.09±0.53 and in group B 2.06±0.64. Post induction mean bishops were 8.92±1.67 and 8.41±1.80 in group A and group B respectively.The mean change in group A was 6.66±1.59 and in group B 6.08±1.59 .(p value, 0.11 NS)

Table 4 shows Data on number of people requiring different method of augmentation in both groups. In

group A , the augmentation of labour was done in patients by ARM 16 (17.71%) , ARM+oxytocin 21(23.59%) and oxytocin infusion 52(58.42%) . In group B ,the augmentation of labour was done in patients by ARM 12 (13.79%) , ARM+oxytocin 26(29.88%) and oxytocin infusion 49(56.32%).The p value for this difference was 0.55(NS). 89% and 87% patients in group A and group B respectively needed augmentation with either ARM or ARM+oxytocin or only oxytocin.The remaining patients 11% and 13% in Group A and Group B either had spontaneous onset of labour or failure of induction.

Table 5 shows comparison of for indication of LSCS in both groups. P value 0.88 shows that differences between incidences of foetal distress , meconium stained liquor , failure of induction and non-progress of labour were statistically non-significant.

Table 6 shows the incidence of perinatal asphyxia with Apgar score ≤7 at 5 minutes and meconium aspiration syndromes were similar in both the groups. 18 % of babies in group A and 12% of babies in group B got admitted in NICU. However the morbidity in both the groups was not statistically significant.

Discussion

This study compared intra-cervical Foley's catheter with PGE2 gel for pre-induction cervical ripening. In present study, the mean age of patients were 25.68±3.84 years and 25.33±3.91 years and mean gestation age were 39.61±1.54 weeks and 39.52±1.3 weeks in Group A and Group B respectively which is comparable with the study done by Hemlata al[16], Anjuman et al[17], Richa et al[18] and Deshmukh et al[19].

The current study shows that the largest need for induction in patient was in the patients with post datism making up 45% and 38% in group A and group B respectively. The group severe preeclampsia made up 15% and 24% in each group respectively. Oligohydramnios contributed to 26% and 32% respectively. This finding was comparable to study by Richa et al[18].

The mean change in bishops score in group A was 5.14±1.60, 5.56±1.89, 5.14±1.60 and 4.94±1.78 in Richa J[18](2017) , V.L.Deshmukh[19](2018), Anjali K[20](2019) and Hemlata[16](2019) respectively which was comparable to present study (6.66±1.59). The mean change in bishops score in group b was 5.10±1.49, 5.56±1.89, 5.16±1.55 and 3.12±1.78 in Richa J[18](2017) , V.L.Deshmukh[19](2018), Anjali K[20](2019) and Hemlata[16](2019) respectively which was comparable to present study (6.08±1.59).

In present study 17.97% , 23.59% and 58.42% patients had been augmented with ARM, ARM+oxytocin and oxytocin respectively in group A. while in group B 13.79%, 29.98% and 56.32% patients had been augmented with ARM, ARM+oxytocin and oxytocin respectively. These results are compatible with Anjuman A[17] (2016), Richa J[18](2017) , V.L.Deshmukh[19] (2018) and Anjali K[20] (2019) and statisytically non-significant.

The mean induction to delivery interval in present study was 13.1±3.05 hours in group A and 13.58±2.51 hours in group B. These results were comparable to Anjuman A[17] (2016) , V.L.Deshmukh[19](2018) and Anjali K[20] (2019) suggesting that induction to delivery interval is similar in both groups.

76%(group A) and 79%(group B) vaginal deliveries were recorded with LSCS rates being 22%(group A) and 18%(group B) and instrumental deliveries rate being 2% (Group A) and 3% (Group B). These findings were similar to Anjali et al[20](78%,16%,6% vs 79%,18%,3%), Deshmukh et al[19](82%,4%,14% vs 79%,3%,18%) and Anjuman et al[17](76%,21%,3% vs 77%, 19%,4%).

Fetal distress was the major indication of LSCS in both groups with 40.90%(group A) and 33.33%(group B). Other indications were MSL 31.81%, 27.77%, FOI 22.72%, 33.33%,NPOL 4.54%, 5.55% in both groups respectively. These results were comparable with studies by Richa et al[18](63% vs 62%), Anjuman et al[17](75% vs 69%)and Deshmukh et al[19](57% vs 61%).

Neonatal outcome in this study included APGAR score at 1 and 5 minutes and admission to NICU. Both methods of inductions are safe for neonates without major difference in neonatal outcome. These results are similar to previous studies.

Conclusion

In conclusion this study has shown that for pre-induction cervical ripening there is no difference in efficacy between intra cervical PGE2 gel and intra cervical Foley's catheter. Also, other factors like induction delivery interval maternal and neonatal outcome and need for oxytocin for further augmentation were similar in both the groups. Both methods are complementary to each other. Foley catheter for cervical ripening is a far cheaper option to PGE2 in term of medicinal/device cost. Because of low cost and easy storage, it is suitable for developing countries with low resources and in settings with limited monitoring facilities. It also has the advantage of simplicity, reversibility and lack of systemic as well as serious side effects.

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