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COMPARATIVE STUDY OF INDUCTION OF LABOUR WITH DINOPROSTONE GEL VERSUS MECHANICAL DILATATION IN UNFAVORABLE CERVIX (LOW BISHOPS SCORE)

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ABSTRACT

Introduction:

Induction of labour is defined as initiation of uterine contractions before spontaneous onset of labour. This observational study compares the effect of prostaglandin E2 (PGE2) and extra amniotic saline infusion (EASI) for pre-labour ripening of unfavourable uterine cervix.

Materials and Methods:

This is a prospective comparative clinical study conducted in the Department of OBGY at Gayatri Vidya Parishad Institute of health Care and Medical Technology from April 2021 to March 2022. A total of 90 patients fulfilling the inclusion criteria were enrolled in this study. They were randomly distributed into two groups after a written informed consent.

Results: 90 patients received dinoprostone gel (group A) and 90 patients received Foleys catheter no.18 (group B). The mean time until cervix ripening was less in group A group (0.0001-p value). The mean time until vaginal delivery was less in the Group A group (p value-0.010) among vaginal deliveries more patients in the Group A group delivered within 24 hours (0.0001-P value.).

Conclusion: PGE2 is associated with greater change in Bishops score as compared with foleys catheter but induction with foleys catheter is not associated with any side effect during induction process.

Key words: Foley's catheter; Induction of labour; Prostaglandin E2 gel

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INTRODUCTION

Induction of labour is defined as initiation of uterine contractions before spontaneous onset of labour. For majority of women labour starts spontaneously and results in vaginal delivery at or near term. However, induction of labour is required when there is risk of continuation of pregnancy either to the mother or to the foetus. The purpose of cervical ripening and induction of labour is to achieve vaginal delivery and to avoid operative delivery by caesarean section. A successful labour induction must result in adequate uterine contractions and progressive dilatation of cervix [1]. It should also result in vaginal delivery, as there is little purpose in bringing about labour as a mere preparation for caesarean section. Labour induction should be carried out with minimum discomfort and risk to both mother and foetus [2].

The two means of cervical ripening prior to labour induction are pharmacological methods and non- pharmacologic methods. Pharmacological methods consist of prostaglandins and they are capable of stimulating uterine contractions resulting in labour. Prostaglandins can be administered by various routes: vaginal, oral and intracervical [3]. In non-pharmacologic methods there are natural and mechanical methods. In natural methods consist of intercourse, breast stimulation, membrane stripping, amniotomy and the mechanical method consists of Balloon devices, hygroscopic dilators.

Mechanical device dilates the cervix by accessing the fetal membrane and pharmacological preparation cause connective tissue softening, cervical effacement and uterine activity [4]. Despite the multiplicity of techniques, there is no universally accepted idea, thus the ideal method of labour induction remains elusive [5]. Prostaglandins as pharmacological agents are used for induction of labour as well as cervical ripening. The commonly used prostaglandins in obstetrics are prostaglandin E1 (PGE1- Misoprostol) and prostaglandin E2 (PGE2- Dinoprostone). Cervical ripening induced by PGE2 is associated with an increase in inflammatory mediators in the cervix and remodelling of the cervical extracellular matrix through a decrease in collagen cross links and increase in cervical glycosaminoglycan [6]. Dinoprostone is the widely used PGE2 analogue that has been approved by the FDA for cervical ripening in women. PGE2 softens the cervix by altering the extra cellular ground substance of cervix. It increases the activity of collagenase and elastase. Exogenous PGE2 also act on cervical smooth muscle thus facilitating cervical dilatation. PGE2 facilitates gap junction formation thus sensitizing uterus to oxytocin, thereby reducing its subsequent use [7].

Mechanical dilatation methods comprise of trans-cervical Foley catheter alone and trans-cervical Foley catheter with EASI for enhanced endogenous prostaglandin secretion [8]. Cervical ripening with extra amniotic balloon catheters possess the advantages of simplicity, low cost, reversibility and lack of severe side effects; however ripening with extra amniotic balloons subsequently requires oxytocin augmentation in many cases and is associated with significant rate of dysfunctional labour and caesarean section. The balloon catheter with EASI probably has a place

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as a cervical ripener, especially when prostaglandins are contra indicated or when uterine hyper stimulation should be avoided such as in cases of fetal IUGR or placental insufficiency. EASI is of low cost, effective and relatively less frequent occurrence of major complications. Studies shows this method can be safely used in patients with previous caesarean section for cervical ripening and labour induction. Different studies conducted so far shows that EASI is as effective as prostaglandins, safe and much cheaper than prostaglandins [9].

MATERIALS AND METHODS

This is a prospective comparative clinical study conducted in the Department of OBGY at Gayatri Vidya Parishad Institute of health Care and Medical Technology from April 2021 to March 2022. A total of 90 patients fulfilling the inclusion criteria were enrolled in this study. They were randomly distributed into two groups after a written informed consent.

Inclusion criteria

The following criteria were included in the study:

- Term gestation (>37 weeks) with cervix not favorable. (Bishops score<6)
- Singleton pregnancy
- Cephalic presentation
- Intact membranes.

Indications for induction

- Elective induction at 40 weeks
- Prolonged pregnancy
- Pregnancy induced hypertension
- Gestational diabetes
- Oligohydramnios
- Intrauterine growth restriction
- Rh isoimmunization.

Exclusion criteria

The following criteria were excluded from the study:

- Presence of cervicovaginal infection
- Rupture of membranes
- Low lying placenta
- Previous uterine scar
- Multiple pregnancy
- Antepartum hemorrhage
- Intrauterine fetal death
- Hypersensitivity to PGs

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PGE2 gel group

About 0.5 mg PGE2 gel instilled into endocervical canal under all aseptic precautions. CTG taken after 1 h and then allowed to ambulate with hourly FHR monitoring or until painful uterine contractions ensued. Bishop's score determined after 6 h. Repeat PGE2 gel instillation done if Bishops score<8

In both the groups, there was no change in the active management of labor.

Outcome measures include

- Change of Bishop's score
- Number of further doses of PGE2 gel required in both the groups
- Induction-delivery interval
- Mode of delivery
- Indication for lower segment cesarean section (LSCS)
- Neonatal intensive care unit (NICU) admission.

Statistical methods

Descriptive statistics were reported using mean±standard deviation for the continuous variable, numbers, and percentage for the categorical variable.

RESULTS

A total of 180 women with gestational ages of 37-42 wks were enrolled in this study. Of the 180 pregnant women, 90 were assigned to the PGE 2 group and 90 to the foley's group.

Table 1: Base line characteristics

	Group 1	**Group 2**	**P value**
Maternal age	25.44±4.23	23.3±5.65	0.095 (not sig)
Gravidity			
G1	45 (50%)	36 (40%)	<0.05 (sig)
G2	15 (16.7%)	25 (27.8%)	<0.05 (sig)
G3	12 (13.3%)	9 (10%)	<0.05 (sig)
G4	18 (20%)	20 (22.2%)	<0.05 (sig)
Parity			
P0	50 (55.6%)	32 (35.6%)	<0.05 (sig)
P1	16 (17.8%)	18 (20%)	<0.05 (sig)
P2	10 (11.1%)	21(23.3%)	<0.05 (sig)
P3	14 (15.5%)	19(21.1%)	<0.05 (sig)

Baseline characteristics of both groups were similar including age, gravidity, parity. The mean gestational age was statistically higher in the PGE2 group; however, this was clinically not significant. Overall indication for induction were also similar across intervention apart from

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more small for gestational age (SGA) or IUGR induction being performed with Foleys catheter. Additionally, cervical station at the time of induction did not differ across intervention group.

Table 2: Labour profile.

Variables	**Group 1**	**Group 2**	**P value**
Initial bishop score	3.36±1.56	3.55±1.65	0.31 (not sig)
Bishop score>6hrs after induction	10.43±4.33	9.56±3.24	<0.001 (sig)
Duration from initiation of induction to active phase of labour (in hrs)	6.88±4.11	8.23±5.47	<0.001 (sig)
Duration from cervix ripening to delivery	7.75±4.54	8.66±6.47	0.021 (sig)

In both groups, considerable improvement occurred in Bishop score 6 hours after initiation of induction, but this progress in PGE2 group was greater than Foleys (P =<0.001, s). The mean time for initiation of the induction to active phase of labour in PGE2 group was shorten (6.88±4.11 hour, Foleys group 8.23±5.47, P=<0.001).

Table 3: Maternal outcome

Mode of delivery (P value-0.0001)	**Group 1**	**Group 2**
Caesarean section	15 (16.7%)	20 (22.2%)
Assisted vaginal delivery	16 (17.8%)	15 (16.7%)
Vaginal delivery	59 (65.5%)	55 (61.11%)
Indication for CS	**Group 1**	**Group 2**
Non-reassuring FHS pattern	4	5
Failed Induction of labour	5	13

Table 4: Maternal complications.

Maternal Complication	**Group 1**	**Group 2**
Meconium stained amniotic fluid	7	9
Fever during delivery	2	1
Hyperstimulation	5	2
Nausea, vomiting	9	1
UTI	1	5

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In group 1, more number of women had complication like fever, nausea, vomiting and UTI as compared to group 2 which is statistically significant. UTI complications are more in Foleys catheter group and fever, nausea, vomiting was common in PGE2 group (Table 4).

Table 5: Neonatal outcome

Neonatal outcome	Group 1	Group 2
Apgar ≤ 4 at min.	2 (6.7)	5 (12.5)
Apgar ≤7 at 5 min	13 (43.3)	10 (25)
Admission to NICU	15 (50)	25 (62.5)

Reasons for NICU admissions were divided into neonatal condition and fetal condition. Neonatal condition includes birth trauma, asphyxia, respiratory difficulties, and jaundice requiring phototherapy. Fetal condition was defined as growth restriction or congenital abnormalities.

As was expected, Bishop score improved significantly in both groups after treatment. The foley catheter intervention took a longer time than the Pg group to ripen the cervix, indicating more favorable outcome with PG a shorter ripening time and induction time with foley catheter has being reported in several studies.

An observation made in the study was a tendency towards more frequent Caesarean section is response to cervical dystocia among the women administered with the foleys catheter.

DISCUSSION

This study was undertaken to compare the efficacy, safety and patient satisfaction of two methods of induction in pregnant women with unfavourable cervix: prostaglandin gel, a single Foley catheter. Mechanical methods were as effective as biochemical methods of cervical ripening in women undergoing induction of labour and had fewer adverse effects. Caesarean delivery was required in more than a third of births with no difference between modes of cervical ripening.

Furthermore, one quarter of all neonates were admitted to the NICU (which likely reflects local unit policies as many of these admissions were for maternal reasons). There was no difference in NICU admission rates between groups; however, measures of newborn wellbeing were significantly worse for women receiving prostaglandin gel. While no adverse reactions occurred with the single balloon catheter, PGE2 gel for cervical ripening was associated with increased rates of uterine hyperstimulation, FHR pattern abnormalities and an increased need to perform fetal scalp blood sampling. Further, PGE2 gel was associated with increased rates of fetal acidaemia in cord arterial blood collected after delivery with lower pH and pO2 values and higher pCO2 values compared to the mechanical methods of cervical ripening. These data

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suggest increased rates of respiratory acidosis after cervical ripening with PGE2 gel, probably secondary to the increased rates of uterine hyperstimulation seen with this cervical ripening technique.

Although the shift in blood gas distributions towards acidaemia is concerning, of more concern is the observation that four of the five cases of severe acidemia occurred in the PGE2 arm of the study. To our knowledge, a very few studies were done comparing methods of induction of labour to report umbilical cord blood gases on all neonates at delivery. This study was not powered to address the issue of fetal acidaemia and these results should be viewed with caution. However, the data presented suggest that this is an important outcome for future studies optimising methods of cervical ripening and induction of labour.

Although patient satisfaction scores were similar in the three groups, women reported significantly lower pain scores with the single balloon catheter than either PGE2 during the 12–18 hours of cervical ripening. With no difference in effectiveness between ripening methods, it appears that the single balloon Foley catheter is the most cost-effective method of induction with fewer side-effects and a cost substantially less than either PGE2 gel. Although other prostaglandin preparations such as tablets or pessaries are less expensive than PGE2 gel, all have similar efficacy and incidence of adverse reactions [10].

This study was done to compare single balloon catheters and a prostaglandin preparation in pregnant women with unfavourable cervix.. In contrast, previous case series indicated good success rates; however, the findings of two small randomised controlled trials comparing with vaginal prostaglandins were equivocal possibly because of small sample sizes and mixed parities [11]. The present study also found some women experienced pain and difficulty voiding with the Foley catheter is likely to be more acceptable to women undergoing cervical ripening. The finding of no difference in caesarean section rates is consistent with previous randomised controlled trials comparing balloon catheters with vaginal prostaglandins [12].

Similarly, uterine hyperstimulation with prostaglandin induction has been reported previously but differences in neonatal outcomes identified in this study have not been investigated adequately [13,14]. The absence of effect of either Bishop Score or FFN (on the success of induction of labour or length of labour) may be explained by the inclusion criteria for the study, namely, the requirement of an unfavourable cervix. This contrasted with previous studies of samples with a range of Bishop Scores prior to induction of labour [15]. Perhaps the reason for the difference in our study is a lack of sensitivity of the Bishop score to success of induction of labour within a subgroup of women with unfavourable cervices. Furthermore, the lack of association between FFN and caesarean section is consistent with a previous study of nulliparous women and reflects the differences in induced labour between nulliparous and multiparous women [16].

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Conclusion

Induction of labour is associated with high rates of maternal and neonatal complications in the nullipara with unfavourable cervix. Outcomes are likely to be considerably improved if induction can be deferred until after ripening has commenced by natural means. When maternal or fetal condition indicates the need for induction of labour, our data suggest that a single balloon catheter is the safest, least expensive and most acceptable method of cervical ripening in nulliparous women with unfavourable cervix but induction with PGE2 gel ,the induction_delivery interval is less.

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