Original Research Article

Comparative study of induction of labour with dinoprostone gel versus mechanical dilatation in unfavorable cervix (low Bishops Score)

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Abstract

Background: Induction of labour is defined as initiation of uterine contractions before spontaneous onset of labour. This observational study compares the effect of prostaglandin E_2 (PGE2) and extra amniotic saline infusion (EASI) for pre-labour ripening of unfavourable uterine cervix. **Methods:** This is a prospective and randomised study was conducted in the Department of Obstetrics and Gynaecology, in a tertiary care teaching hospital over a period of six months. Patient admitted for induction of labour were randomized to receive intravaginal dinoprostone or intracervical Foley's catheter. Patient not entering active labour and having rupture membranes or arrest of dilatation received IV oxytocin. **Results:** A total of 140 women with gestational ages of 37-42 wks were enrolled in this study. Of the 140 pregnant women, 70 were assigned to the PGE 2 group and 70 to the foley's group. 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 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. **Conclusions:** Group A was associated with more rapid cervical ripening, shorten induction to vaginal delivery interval and greater no. of vaginal deliveries within 24 hours.

Keywords: Cervical ripening, Bishop's score, Extra amniotic saline infusion, Labour induction, Prostaglandin E2.

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 herbal supplements, intercourse, breast stimulation, membrane stripping, amniotomy and the mechanical method consists of Balloon devices, hygroscopic dilators, acupuncture.

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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 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].

Objectives of the study were the present study was undertaken with the aim to compare the effect of PGE2 and EASI for prelabour ripening of unfavourable uterine cervix in pregnant women. This study also compares the effects of PGE2 and EASI on maternal complications and neonatal outcomes.

Methods

This is a prospective and randomised study was conducted in the Department of Obstetrics and Gynaecology, in a tertiary care teaching hospital over a period of six months. Induction of labour employing cervical administration of dinoprostone (PGE2) or cervical dilatation by Foleys catheter (bard catheter) were compared. The criteria for inclusion were pregnancy between 37 to 42 weeks gestation, had a singleton pregnancy with the fetus in vertex presentation, with one or more of the common indication for induction of labour including post term pregnancy, premature rupture of membrane, preeclampsia, oligohydramnios, diabetes and psychological parameters. In additions, absences of spontaneous contraction and Bishop score of equal or less than 5 were also required. The criteria applied for exclusion from the study where contraindication for the administration of PG and/or for vaginal delivery, or previous caesarean section or other form of uterine surgery, breech presentation, signs of infections and or the necessity for immediate delivery as indicated by, for example, pathological CTG at the time of admission. Who fulfilled appropriate criteria were invited to participate in the study and those who agreed gave their informed consent.The women assigned to dinoprostone group, received 2mg of dinoprostone gel intracervically. The women in the 2nd group a Bard catheter no.18 was inserted through the cervical canal with visualization of the cervical os during examination with a speculum. Once past the internal os, the balloon was filled with 50 ml of sterile water and the catheter tapped to an inner thigh to maintain traction. The position and traction of balloon were checked on once or twice on each hour and the catheter remained in place until the balloon was expelled spontaneously.

All the women were monitored clinically for the progress of labour and fetal wellbeing. Partogram was maintained in all cases. When the Bishop score attained a value of equal to or more than 7, the membranes were ruptured artificially or, in cases of preterm rupture, oxytocin were administered if necessary. If Bishops score remains unfavorable equal or less than 5 after 18 hours of treatment in any group there m/m in those patients was further individualized.

The primary outcome measure was induction to delivery interval. Secondary outcome was the incidence of instrumental delivery (including cesarean section), uterine hyper stimulation with or without abnormalities in fetal heart rate, staining of the amniotic fluid with meconium requirement for augmentation with oxytocin and occurrence of postpartum bleeding. The neonatal outcome recorded were the apgar score 5 min. after birth a necessity for admission to the neonatal intensive care unit.

Statistical analysis

The groups were compared by using chi square test and unpaired student T test. Statistical significances were defined as $P < 0.05$.

Results

A total of 140 women with gestational ages of 37-42 wks were enrolled in this study. Of the 140 pregnant women, 70 were assigned to the PGE 2 group and 7 0 to the foley's group.

Table 1: Maternal age

Age	Group 1	Group 2	P value
Maternal age	24.51±3.40	25.01±4.19	0.094

Table 2: Gravidity of the subjects

Gravidity	Group 1	Group 2	P value
G1	33 (47%)	29 (41.4%)	0.0001
G2	23 (32.5%)	27 (38.5%)	0.0001
G3	11 (15.7%)	9 (12.8%)	0.0001
G4	3 (4.2%)	5 (7.1%)	0.0001

Table 3: Parity of the subjects

Parity	Group 1	Group 2	P value
P0	41 (58.5%)	33 (47.4%)	0.0001
P1	19 (27.1%)	23 (32.8%)	0.0001
P2	7 (10.0%)	11 (15.7%)	0.0001
P3	3 (4.2%)	3 (4.2%)	0.0001

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 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.

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 (4.32±2.08 hours, Foleys group 7.26±3.38, P=0.001).

Table 4: Labour profile

Variables	Group 1	Group 2	P value
Initial bishop score	2.01±0.73	2.43±0.78	0.652
Bishop score>6hrs after induction	8.11±2.10	7.21±1.71	0.0001
Duration from initiation of induction to active phase of labour (in hrs)	4.32±2.08	7.26±3.38	0.0001
Duration from cervix ripening to delivery	5.63±2.56	6.14±4.34	0.0001

In Table 4 illustrates interval time from beginning of cervical ripening to vaginal delivery in both groups. There was significant difference in the caesarean rate and indication of caesarean between the two groups. The rate of caesarean section is more in group 2 as compared to group 1.

Table 5: Maternal outcome

Mode of delivery	Group 1	Group 2
Caesarean section	9	14
Assisted vaginal delivery	3	5
Vaginal delivery	58	51

Table 6: Indication for Cesarean Section

Indication for CS	Group 1	Group 2
Non-reassuring FHS pattern	4	4
Failed Induction of labour	4	21

Table 7: Maternal complications

Maternal Complication (P value- 0.002) P value significant	Group 1	Group 2
Meconium stained amniotic fluid	6	7
Fever during delivery	2	1
Hyperstimulation	3	1
Nausea, vomiting	9	1
UTI	1	4

In group 1, 12.8 % of women had complication like nausea, vomiting as compared to 1.4% in group 2 which is statistically significant (p = 0.001). UTI complications are more in Foleys catheter group and fever, nausea, vomiting was common in PGE2 group in Table 7.

Table 8: Neonatal outcome

Neonatal outcome	Group 1	Group 2
Apgar ≤ 4 at min.	1	2
Apgar ≤7 at 5 min.	9	13
Admission to NICU	8	17

In table 8, no significant differences between the groups with respect to neonatal outcome were noted. On average 11.4% of neonates require admission to neonatal nursery or special care unit with significantly more admission in Foley's group (24.2% vs 11.4%, p = 0.01).

Discussion

In modern obstetrics, more than 22% of pregnant women undergo labour induction[10]. A cross-sectional population based analysis by Davey *et al* found the Caesarean delivery rate following labour induction to be 26.5% whereas it was 12.5% in women with spontaneous onset of labour[11]. Though Caesarean delivery may be lifesaving in various circumstances for the mother, the baby or both, the rapid increase in Caesarean rate over the last many years without a concomitant decrease in maternal, foetal morbidity or mortality raises a serious concern whether the caesarean section is overused[12].

As observed in the Obstetric Care Consensus 2014 by the American College of Obstetrician and Gynaecologists and the Society for Maternal and Foetal medicine, contemporary labour may be slower than previously thought. Prolonged latent phase (more than 20 hours in primigravida or more than 14 hours in multigravida) should not be an indication for caesarean section. Hence caesarean deliveries for failed induction of labour can be avoided by allowing longer duration of the latent phase (up to 24 hours or longer) and administering oxytocin for at least 12-18 hours after membrane rupture before deeming induction a failure if maternal and foetal status allow [13]. According to WHO, the ideal rate for Caesarean delivery should be 10-15%. As supported by the obstetric Care Consensus on Safe Prevention of the Primary Caesarean, use of cervical ripening agents such as misoprostol, dinoprostone, Prostaglandin E2 gel, Foleys catheter, laminaria tent reduce the rate of Caesarean rate[14]. In our study we have sequentially used Foleys catheter intra cervically and dinoprostone gel in an attempt to achieve cervical ripening in cervices with poor Bishops followed by initiation of uterine contractions. Studies by various contemporary authors who have compared use of Foleys catheter versus Dinoprostone gel as ripening agent were reviewed and found that the induction- delivery intervals were in the range of 10-19 hours in the first group and 11-16 hours in the second group[15].The need for Caesarean delivery was found to be lesser. These findings were consistent with those of other authors, like Penagaluru Radha *et al* showing 18 % for Foleys group and 32 % for Dinoprostone group[16]. Mumtaj M *et al* showed that 11.5% of para-1 patients of Foleys Group whereas 40.9% of the para-1 patients of PGE2 Group delivered by caesarean section[17].

Reasons for nursery 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.On comparison of the two groups regarding maternal complications like fever, hypers timulation, diarrhoea and vomiting no statistically significant differences were found. These finding were consistent with those of Dileep P *et al* and Penagaluru Radha *et al* but contrary to the findings of Gayatri Mathuriya *et al*, where Dinoprostone group had significantly more minor complications[18].

Conclusion

For most low risk pregnancies, compared to vaginal delivery, caesarean delivery appears to pose greater risk of maternal mortality and morbidity as well as long term risks associated with subsequent pregnancies. In this context, intracervical foleys catheter may aid to lower the caesarean delivery rate. Though sequential usage may increase the overall induction delivery interval, it does not appear to increase the incidence of neonatal sepsis, admission to the neonatal unit or the incidence of puerperal or intra partum fever. Moreover, Foleys catheter is less costly, can be preserved in room temperature and can be used in conditions where Dinoprostone gel is not advised. By using Foleys catheter as the initial ripening agent, we can also decrease the total usage of dinoprostone gel.Hence in women in whom induction of labour is deemed necessary in the presence of poor Bishops score, intracervical Foley's catheter may be used as a ripening agent alone or sequentially with other agents like dinoprostone gel to achieve a higher vaginal delivery rate without hampering maternal of neonatal safety.

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