Research article

Efficacy and safety of extra amniotic insertion of Foley catheter verses intra cervical application of PGE_2 gel in pre-induction cervical ripening among primi mothers at 40 weeks +5 days or beyond – a randomized controlled study

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Abstract

Objectives: The aim of this study was to compare the efficacy, safety and side effects of extra amniotic insertion of Foley catheter and intra-cervical application of prostaglandin E_2 vaginal gel (PGE_2) among primi mothers who were 40 weeks or beyond, as a pre induction ripening method.

Method: This randomized study was conducted at Obstetrics ward, Kandy Teaching Hospital, between August 2010 to March 2011. Hundred and fourty-five mothers were randomly allocated to two groups. Age, BMI, period of gestation and, pre ripening Bishop's score were measured as base line features to compare two groups. Group A (n=72) was ripened with prostaglandin E_2 vaginal gel (Dinoprostone 0.5 mg) and Group B (n=73) with insertion of Foley catheter (18 G and filled with 70 ml of distilled water) without tension. Primary outcome measures were spontaneous onset of labour within 24 hours and the mode of delivery. Maternal and fetal adverse effects were measured as secondary outcomes. Maternal age, period of gestation, pre induction cervical ripening Bishop's score and maternal BMI were compared as baseline characters of two groups. As measures of efficacy, spontaneous onset of labour, vaginal delivery rate and caesarean section rate were compared. Maternal and fetal adverse effects were used to compare the safety of the two methods.

Results: Mean maternal ages were 27 and 28 years in group A and B respectively. Mean period of gestation was 40 weeks +5 days in both groups. Mean pre ripening Bishop's scores in group A was 4.24 ± 0.41and 4.63 ± 0.38 for group B. BMI of group A was 26.9 ± 1.43Kg/m^2 and 27.2 ± Kg/m^2 in group B. However, a significant difference was not observed between these two groups. While mothers in group A had 30.5% spontaneous onset of labour, only 24.6% mothers went into spontaneous onset of labour (*p=0.78*) in group B. Vaginal delivery rates were 77% and 72% in group A and B respectively (*p=0.78*). Respective Caesarean section rates of group A and group B were 22.8% and 27% (*p=0.64*).

Mothers who had PGE_2 had significantly higher chances of experiencing side effects (44%) in compared to mothers who had Foley catheters (22%) (*p=0.016*). Mothers who had PGE_2 had significantly higher rates of uterine hyper-stimulation (*p=0.01*), nausea and vomiting (*p=0.03*) and fever more than 38 C° (*p=0.03*) while post-partum haemorrhage was not significant (*p=0.071*). Similar rates of meconium at ARM, fetal distress, APGAR<7 at 5 min and SBU admissions were experienced by fetuses and neonates in both groups (*p=0.63*).

Conclusion: Insertion of Foley catheter to extra amniotic space is as effective as intra-cervical application of PGE_2 gel for pre induction cervical ripening. Due to lower maternal adverse effects, extra amniotic insertion of Foley catheter is safer than intra-cervical application of PGE_2 gel.

Key words: pre induction cervical ripening, Foley catheter, PGE2 gel, induction of labour

Sri Lanka Journal of Obstetrics and Gynaecology 2020; **42:** 61-67

DOI: http://doi.org/10.4038/sljog.v42i2.7910

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Received 21st March 2020

Accepted 10th April July 2020

Introduction

Artificial initiation of labour prior to its spontaneous onset for the purpose of delivery of feto-placental unit is known as induction of labour (IOL)[1]. Successful IOL depends on the adequate level of pre induction cervical ripening, the process of preparing the cervix by cervical effacement and dilatation. It is measured by modified Bishop's score[2]. When continuations of pregnancy jeopardise the maternal or fetal health, IOL has shown a reduction in both maternal and perinatal adverse outcomes. In the United Kingdom, the rate of IOL ranges from 6 to 25% with the average being about 20%[3]. Sri Lanka has a rate of IOL of 37.5% which is one of the highest rates in the world[4].

In the course of normal pregnancy, ripening of the cervix includes softening and dilatation of the cervix, due to decreased collagen and glycosaminoglycan concentration and increased amount of water. These changes are accelerated towards the end of the pregnancy and leads to the onset of labour[5]. When nature failed to do so at term or when induction of labour needed early, artificial ripening of the cervix is essential for the induction of labour.

Different agents including chemical and mechanical methods are being used worldwide for cervical ripening. Amongst, most commonly used agent is prostaglandin E_2 (PGE_2). Synthetic prostaglandins mimic normal physiological process of cervical ripening and increases the sensitivity of the myometrium to Oxytocin. It reduces the induction to delivery interval, compared with placebo, when used as part of the induction process. However, due to the systemic absorption of this agent, side effects including nausea and vomiting, initiation of uterine contractions can occur. Potential complications of induction of labour with PGE_2 includes failed induction, uterine hyperstimulation, uterine rupture and increased risk of delivery by a caesarean section[5,9,10].

Intra cervical Foley catheter act as a mechanical dilator of the cervix and the lower segment of the uterus and it indirectly induces localized secretion of prostaglandin due to activated acute inflammation[6,7,8,11]. Foley catheter is less costly in compared to PGE_2 intracervical gel and there is no increased risk of infection as well.

The aim of this study was to compare the efficacy and safety of PGE_2 intracervical gel insertion with insertion of Foley catheter into the extra amniotic space, at 40 weeks+5 days of gestation or beyond. According to ward protocol, pre-induction ripening was started at 40+5 days or beyond.

Methods

This randomized controlled trial was conducted at the Teaching Hospital Kandy from August 2010 to March 2011. Hundred and fourty-five primi mothers who needed cervical ripening due to unfavourable cervix were randomized in to two groups (Group A and B). Group A (n=72) was ripened with prostaglandin E_2 vaginal gel (Dinoprostone 0.5 mg) and Group B (n=73) with insertion of Foley catheter. Inclusion criteria for the study was 40 weeks +5 days or beyond, primi mothers who has singleton pregnancies, vertex presentation, intact membranes, with satisfactory non-stress CTG and modified Bishop's score 6 or less. Mothers who had contra-indications for vaginal delivery, previous uterine surgeries, multiple pregnancies, unexplained ante partum haemorrhage, asthma, known allergy to prostaglandins and who already had artificial separation of membranes were excluded.

Eligible mothers who fulfilled the entry criteria were consented with informed written consent and randomized with computer generated random numbers to two groups. Age, Body Mass Index (BMI), period of gestation and pre induction Bishop's score were documented as base line features to compare the two groups.

Primary outcome measures were spontaneous onset of labour within 24 hours and mode of delivery. Secondary outcome measures were maternal adverse outcomes (uterine hyper stimulation, nausea and vomiting, fever more than 38°C, post-partum haemorrhage due to uterine atony) and fetal adverse outcomes (meconium at ARM, fetal distress, APGAR score less than 7 at 5 min, requirement of special baby care unit admissions).

All participants had pre-ripening 20 min non-stress CTG and Bishop's score assessment. Mothers selected to group A were treated with intra cervical insertion of 0.5 mg of Dinaprostone (PGE_2) gel according to manufacturer's (Cervi-prime) instructions. Fetuses were monitored with hourly heart rate monitoring and 20 min CTG at 2, 8 and 12 hours. Group B was treated with insertion of 18 G Foley catheter to extra amniotic

space through the cervix under strict sterile conditions. Balloons were filled with 70 ml of distilled water. Then catheter was taped on to the women's inner thigh to maintain the traction. Fetal monitoring was done with hourly fetal heart rate monitoring and CTG at 6 hours and 12 hours after inserting the Foley catheter, according to the ward protocol. Catheter was removed 24 hours after insertion, if it did not fall spontaneously.

Mothers who had spontaneous onset of labour within 24 hours of pre-induction ripening, were taken into the labour ward and monitored using a national partograph. Progression of labour was assessed 4 hourly. If progression of labour was inadequate, it was augmented with artificial rupture of membranes (ARM) followed by commencing intravenous oxytocin after two hours.

Mothers who did not have spontaneous onset of labour, ARM done and intra-venous oxytocin was started at the same time. Mothers who needed induction or augmentation were monitored with continuous CTG monitoring. All participants and fetuses were closely monitored for side effects. Uterine hyper stimulation was defined by either the occurrence of five or more contractions in a 10-minute period or a contraction lasting at least 2 minutes with or without changes in FHR patterns. Fetal heart rate was considered abnormal if there was persistent reduced baseline variability, tachycardia, late decelerations or variable decelerations.

Failed induction of labour was defined as inability to rupture the membranes 24 hours after the insertion of PGE_2 gel or when the cervix does not dilate beyond 3 centimetres despite adequate and appropriate oxytocic stimulation over 6 hours in both groups. Even though, some previous studies[21,22,23] had used a repeat dose of PGE_2 gel after 6 hours and keeping Foley catheter for 48 hours before starting the induction process, we used only single dose of PGE_2 gel and Foley catheter was kept only for 24 hours, as we wanted to adhere to the ward protocol on induction of labour.

The study was approved by the Ethical Committee of the Kandy Society of Medicine.

Results

Basic demographic characteristics (Table 1) were compared in both groups. Mean maternal ages were 27 and 28 years for group A and B respectively. In both groups, mean period of gestation was 40 weeks +5 days. Respective mean pre ripening Bishop's scores in group A was 4.24 ± 0.41while it was 4.63 ± 0.38 in group B. BMI of group A was 26.9 ± 1.43Kg/m^2 and 27.2 ± Kg/m^2 in group B. However, observed differences were not large enough to show a significant difference between two groups.

While mothers in group A had 30.5% (n=22) spontaneous onset of labour, only 24.6% (n=18) mothers went into spontaneous onset of labour in group B (*p=0.78*). Nearly two thirds (69.5%, n=50) of mothers required induction and augmentation in Group A, while 75.4% (n=55) mothers required the same in group B. Difference observed was not significant (*p=0.64*).

Fifty-six mothers (77%) in Group A had vaginal birth compared to group B where 53 mothers (73%) delivered vaginally, which was not statistically significant (*p=0.78*).

Table 1. Baseline characteristics of two study groups (n=145)

Baseline character	PGE_2 gel (n=72)	Foley catheter (n=73)	P value
	Mean (SD)	Mean (SD)	
Maternal age (years)	27 (3.2)	28 (3.6)	0.14
POG (weeks)	40+5 (0.41)	40+5 (0.43)	0.73
Pre ripening Bishop's score	4.24 (0.41)	4.63 (0.38)	0.52
BMI (Kg/m^2)	26.9 (1.43)	27.2 (1.54)	0.83

Table 2. Outcome of cervical ripening in two groups (n=145)

Outcome of cervical ripening	PGE_2 gel (n=72) Number (%)	Foley catheter (n=73) Number (%)	P value
Spontaneous onset of labour	22 (30.5%)	18 (24.6%)	0.78
Need induction and augmentation	50 (69.5%)	55 (75.4%)	0.64
Total	72	73	

Table 3. Delivery outcomes of the two study groups (n=145)

Base line character	PGE_2 gel (n=72) Number (%)	Foley catheter (n=73) Number (%)	P value
Vaginal delivery	56 (77%)	53 (72%)	0.78
Caesarean section	16 (22.2%)	20 (27%)	0.64
Total	72	73	

Sixteen mothers (22.2%) in Group A underwent CS compared to twenty mothers (27%) in Group B, which is statistically not significant (*p=0.64*). Six mothers (16.7%) from group A and nine mothers (25%) from group B had caesarean section due to failed induction (*p=0.083*). Five (13.9%) mothers from group A and three (8.3%) mothers from group B required emergency caesarean section due to foetal distress (*p=0.078*) while five (13.9%) and eight (22.2%) mothers required caesarean section due to lack of progress in group A and group B respectively *(p=0.062*).

Total number of 47 mothers experienced side effects (Table 4). Uterine hyperstimulation (UHS) was noted in 4 mothers (8.5%) of group A while none of the mothers in group B experienced uterine hyper stimulation (*p=0.01*). While 18 (38.3%) mothers experiencing nausea and vomiting in group A, only 8 (17%) mothers experienced it in group B (*p=0.03*). Four (8.5%) mothers in group A and one (2.1%) mothers in group B had fever during the process of ripening, induction or augmentation (*p=0.032*). Post-partum haemorrhage was noted in 4 (8.5%) mothers in group A and 6 (12.7%) mothers in group B (*p=0.071*). Uterine hyper stimulation, nausea and vomiting, maternal fever more than 38°C was significantly higher with mothers of group A, compared to group B but no difference noted in the risk of post-partum haemorrhage.

Fifty-nine fetal and neonatal complications were noted in the study population during the study period (Table 6). Meconium stained liquor was noted in 10 (17%) mothers in group A and 8 (13.5%) mothers in group B when rupturing the fetal membranes (*p=0.21*). Five foetuses (8.4%) in group A, and three (5.1%) in group B were distressed during ripening period (*p=0.07*). APGAR score at 5 minutes was less than 7 in 2 (3.4%) infants in group A and 3 (5.1%) infants in group B (*p=0.81*). Twelve (20.3%) and sixteen (27.1%) neonates were admitted to special baby care unit from group A and group B respectively (*p=0.09*).

Table 4. Maternal side effects of two study groups (n=47)

Maternal side effects	PGE_2 gel (n=32)	Foley catheter (n=15)	P value
	Number (%)	Number (%)	
UHS	4 (8.5 %)	0 (0%)	0.01
Nausea and vomiting	18 (38.3 %)	8 (17.0 %)	0.03
Maternal fever (>38°C)	4 (8.5%)	1 (2.1%)	0.032
PPH	4 (8.5%)	6 (12.7 %)	0.071
Total	32 (68.2%)	15 (31.8%)	0.016

Table 5. Foetal and neonatal effects of two study groups (n=59)

Foetal and neonatal side effects	PGE_2 gel (n=29)	Foley catheter (n=30)	P value
	Number (%)	Number (%)	
Meconium at ARM	10 (17.0%)	8 (13.5%)	0.21
Foetal distress	5 (8.4%)	3 (5.1%)	0.07
APGAR <7 at 5 min	2 (3.4%)	3 (5.1%)	0.81
SBU admission	12 (20.3%)	16 (27.1%)	0.09
Total	29 (49.1%)	30 (50.9%)	0.63

Discussion

The results of this study has demonstrated that, both, intra cervical application of PGE_2 gel and insertion of Foley catheter to extra amniotic space are equally effective in pre induction cervical ripening, in terms of spontaneous onset of labour and successful vaginal delivery. These results are similar to studies carried out in the past[14,15]. Thirty-six mothers (24.8%) had emergency caesarean section. Majority of caesarean sections were due to failed induction (n=9) and mothers who had Foley catheter as ripening method (n=6, *p=0.083*). On the other hand percentage of caesarean section due to fetal distress was higher in mothers who had PGE_2 gel as the ripening method (*p=0.078*). Similar observations were seen in the previous studies[16,17]. Similar to the previous studies, maternal side effects, including, uterine hyperstimulation, nausea and vomiting were higher with mother's who had PGE_2 gel[14,16]. A study done by Tofatter K.F. et. al. showed higher febrile morbidity in mothers who had Foley's catheters. Compared to the previous studies where higher febrile morbidities in the Foley's group, we observed significantly lower febrile morbidity in Foley group. This may be due to the adherence of sterile techniques, when inserting the Foley catheter. Post-partum haemorrhage (PPH) risk was not assessed in other studies. In our study there was no significant difference between two study groups with regards to Post Partum Haemorrhage (*p=0.071*). Uterine hyperstimulation was common in our study similar to the previous studies is more likely due to the adverse effects of PG[12,15].

In terms of fetal side effects, there was no significant fetal effects in both groups[16,17,18,19,20]. However, babies who were delivered by mothers in group B, had higher risk of admission to specialised baby care unit. Neither method had mortalities.

Conclusion and recommendations

Insertion of Foley catheter into the extra amniotic space is as effective as transcervical application of PGE_2 gel in terms of efficacy of pre induction cervical ripening. It is more economical due to low cost and need less frequent monitoring due to lower risk of uterine hyperstimulation. It is well tolerated by mothers as well as fetuses with less side effects. Only primigravid mothers, who were 40 weeks+5 days or above, participated for this study. Therefore, more studies are needed to explore and identify mothers who need pre-induction cervical ripening due to other indications.

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