

A Comparative Study of Extra-Amniotic Saline Infusion (EASI), Foley's Catheter and Prostaglandin E₂(PGE₂) gel for Pre-Induction Cervical Ripening

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ABSTRACT

Introduction: Cervical ripening is essential for successful induction of labor. The aim of the study is to compare the efficacy, safety and cost-effectiveness of extra-amniotic saline infusion, Foley's catheter and intra-cervical PGE₂ gel for pre-induction cervical ripening.

Methods: A total 150 women having indications of labor induction were randomly assigned equally into three groups: EASI, Foley's catheter and PGE₂ gel. Eligible full-term pregnancy with Bishop score 4 or less was recruited for the study. Computer generated randomization method and random numbers were used to allocate cases into three groups. Data were analyzed by SPSS. The induction to cervical ripening interval, induction to delivery time, changes in the Bishop Score, mode of delivery and cost were assessed.

Results: Majority of the cases was primigravida (67.3%) and the most common indication of induction was postdated pregnancy (72%). The mean time for induction to cervical ripening interval was shorter in Foley's catheter and EASI than PGE₂ (6.92 & 5.69 vs 11.08 (P<0.006). Majority of cases in Foley's catheter and EASI achieved the Bishop score of 7 or more within 24 hours of induction as compared to PGE₂ (88% & 84% vs 54%, P<0.000). The mean induction to delivery time is found shorter in EASI and Foley's catheter than PGE₂ (14.95hrs & 16.84hrs vs 23.18hrs).

Conclusions: Foley's catheter and extra-amniotic saline infusion (EASI) are the most efficacious, cost effective and safe methods of cervical ripening as compared to PGE₂ gel.

Keywords: cervical ripening; EASI; foley's catheter; induction of labor; PGE₂.

INTRODUCTION

There are many cases which require induction of labor for several reasons.² Induction of labor is the artificial initiation of contractions before starting spontaneous labor mainly to achieve successful vaginal delivery within 24 to 48 hours. Cervical ripening is the process to soften, efface or dilate the cervix by using pharmacological or other methods to increase the chance of a vaginal delivery.³ There are several methods for cervical ripening such as natural non-invasive (hot bath, Castrol oil), mechanical (balloon catheter, hygroscopic dilators, EASI), surgical methods and pharmacological agents (prostaglandin E₂,

misoprostol/prostaglandin E1).⁴⁻⁶

Both mechanical dilator and pharmacologic procedures have been found successful to ripen the unfavorable cervix⁷. Many studies have shown that mechanical agents such as balloon catheter is as efficacious as other agents.⁸⁻¹² The main objective of the study was to compare the three different methods of preinduction cervical ripening: Extra-amniotic saline infusion (EASI), Foley's catheter and Cerviprime (PGE₂) gel in terms of efficacy, safety and cost effectiveness.

METHODS

The study was conducted in the department of obstetrics and gynecology in B.P. Koirala Institute of Health Sciences, Dharan, Nepal. A total 150 women having indications for induction of labor were recruited in this study. There were 50 participants in each group (Cerviprime (PGE₂) gel, Foley's catheter and Extra-amniotic saline infusion).

Inclusion criteria: (1) all full-term pregnancies (>37 weeks) associated with complications such as intrauterine growth restriction (IUGR), diabetes mellitus, Rh- negative mother, severe PIH (pregnancy induced hypertension) and (2) all postdated pregnancies (>41 weeks)-with single live fetus in cephalic presentation having initial bishop score of 4 or less and not in labor, were included in the study.

Exclusion criteria: known cases of hypersensitivity to prostaglandins, bronchial asthma, severe medical diseases, abruptio placenta, placenta previa, chorio-amnionitis, premature rupture of membrane (PROM), bad obstetric history (BOH), cephalo-pelvic disproportion (CPD), previous uterine scar, multifetal pregnancy, malpresentation, intrauterine fetal death (IUFD) and congenital fetal malformations were excluded from the study.

Randomization: Eligible 150 participants were selected and randomized by computer generating randomization. All participants were divided into ten blocks, each with fifteen cases. In each block the cases were randomized and allocated to the particular group of induction method and participants were allocated to the specific group of cervical ripening method. There were three groups: Extra-amniotic saline infusion (EASI), Foley's catheter and Cerviprime (PGE₂) gel. There were 50 participants in each group.

Data Analysis

Data were edited and coded then statistical analyses were carried out using SPSS. Chi square test and Kruskal-Wallis H (equivalent to Chi square) test applied. P<0.005 was used to define statistical significance.

RESULTS

There were 150 women with term pregnancy involved in this study. There were 50 (33.3%) participants in each method of induction such as: Extra -amniotic saline infusion (EASI), Foley's catheter and PGE₂ gel. Majority of participants (78%, n=116) were aged 20-30 years, primigravida (67.3%, n=101) and 41 or more weeks gestation (78%, n=108). Postdated pregnancy was the most common indication of induction (72%) followed by hypertensive disorder (14.7%) and oligohydramnios (7.3%)

Indications of induction	No.	%
Post-date	108	72.0
Hypertensive disorder (PIH)	22	14.7
Gestational diabetes	2	1.3
Oligohydramnios	11	7.3
Intrauterine growth restriction	1	0.7
Rh negative	1	0.7
Non-reactive NST	5	3.3
Total	150	100.0

This study found that EASI had the shortest induction to cervical ripening time interval as shown in (Table 2).

Methods of induction	No.of patients	Mean (hours)	variance	Std deviation
PEG ₂ gel	50	11.0816	94.1494	9.7031
Foley's Catheter	50	6.9231	32.5528	5.7055
EASI	50	5.6939	11.7689	3.4306

(Kruskal-Wallis H test, P< 0.0061)

Bishop score of 7 or more within 24 hours of induction was taken as an indicator of successful result of preinduction cervical ripening method. Both Foley's catheter and EASI were found more successful than PGE₂ el.

Table 3. Methods of Induction Versus Cervical Ripening (Success Rate) within 24 hours

Methods of induction	Favorable (success)	Unfavorable (unsuccess)	Total
PEG ₂ gel	27	23	50
%	54	46	100.0
Foley's Catheter	44	6	50
%	88	12	100.0
EASI	42	8	50
%	84	16	100.0
Total Nol	113	37	150
%	75.33	24.33	100.0

(Chi Square test, $P < 0.0002$)

Mean induction to delivery time was longer with PGE₂ gel (23.18 hours) as compared to Foley's catheter (16.84 hours) and EASI (14.95 hours).

About 66.6% (n=100) among induced women had vaginal delivery and 33.3% (n=50) cases had lower segment cesarean section.

DISCUSSION

The practice of induction of labor has been common in modern obstetric care when maternal and fetal complications arise.⁷ The practice has been increasing significantly since the early 1990s. The rate of labor induction in Canada reached 21.8% in 2004-2005.³ About 25% of all deliveries at term use induction of labor in developed countries. In developing countries, the rate has seen to be variable.¹³ There are various techniques and agents of cervical ripening and induction of labor as defined in obstetric literatures.⁴⁻⁶ The ideal method must be free from adverse effects on mother and fetus; it should be effective over a reasonably short period, easy to administer and affordable to use.

Prostaglandin is a popular pharmacological agent for cervical ripening. Both misoprostol (PGE₁) and dinoprostone (PGE₂) are in widespread practice. Misoprostol administered intravaginally and intracervical dinoprostone are found to be similarly effective for cervical ripening and induction of labor.¹⁴ Misoprostol as titrated low dose oral solution has been found to be the safest for lowering the risk of caesarean section

and vaginal misoprostol tablet has been found to be the most effective for achieving a vaginal delivery within 24 hours.¹⁵ Mechanical methods such as EASI and Foley's catheter are also gaining popularity in cervical ripening. Several studies have been carried out to compare the efficacy of different methods for cervical ripening and induction of labor. However, the issues on cervical ripening and induction of labor still remain debatable.¹⁶

In this study, EASI and Foley's catheter method were found more effective than PGE₂ gel. Similarly, a randomized controlled trial has also shown that EASI with a Foley's catheter is more effective than PGE₂ vaginal gel.¹⁷ However, another study has shown that cervical ripening is more fast and effective in extra-amniotic balloon with PGE₂ than extra-amniotic saline.¹⁸ In this study, majority of indication for induction of labor was postdated pregnancy (72%, n=108). Other studies have also shown that post-dated pregnancy is the most common reason for induction.^{19, 20} Majority of women undergoing induction of labor in this study were of the age of 20 - 30. This could be because they fall in the suitable child-bearing age.

The results of this study showed that EASI was found more effective method for cervical ripening and induction of labor as compared to PGE₂ gel. Evidences have shown that EASI is more than or as equally effective as PGE₂ for cervical ripening and induction of labor.^{11, 17, 21-23}

Similarly, this study has revealed that Foley's catheter is more effective than PGE₂ gel. Many other studies have also found that Foley's catheter is more or equally effective method for cervical ripening and induction of labor than PGE₂ gel.^{21, 24-27-29} In this study, both EASI and Foley's catheter were found equally effective for cervical ripening. However, some studies have shown that EASI is better effective for cervical ripening than Foley's catheter.^{23, 29}

The mode of delivery was not significantly different among these three methods in this study. However, the occurrence of vaginal delivery was higher in Foley's catheter and EASI than PGE₂

gel. Overall cesarean section rate was only 33.3% which is similar to many other studies.^{11,17,21,23,26}

There is a concern about discomfort and infection in Foley's catheter and EASI methods. In this study, no any maternal and fetal adverse effects were noticed. All three methods were found to be equally safe in this study. It was revealed that EASI and Foley's catheter methods were as safe as prostaglandin agents for cervical ripening; this has also been indicated in various other studies.^{11,22,25,26,29,30}

In this study, Foley's catheter was found to be the cheapest method followed by EASI compared to PGE2 gel. Many other studies have also shown that mechanical methods such as Foley's catheter and EASI are cheaper methods for cervical ripening.^{24-27,30}

CONCLUSIONS

In conclusion, both Foley's catheter and EASI are more efficacious, safe and cheaper methods of cervical ripening and induction of labor as compared to PGE2 gel. These two methods are more practically applicable in low income countries like Nepal because they are significantly cheaper and equally effective. Both methods have significantly shorter ripening time and are safe to use as standard method as PGE2 gel.

Conflict of Interest: None

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