

Comparison of the Efficacy of PGE₂ Suppository and Cervical Foley Catheter with Pre-induction Ripening of the Cervix

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Abstract

Background: An increasing success in induction of labor and subsequent termination of pregnancy in presence of unfavorable cervix requires cervical ripening in order to reduce complications and to diminish the rate of cesarean sections as well as the duration of labor. However, there is no consensus on the efficiency of conventional methods for cervical ripening.

Objective: To determine and compare the effects of PGE₂ suppositories and inflated Foley catheter on pre-induction ripening of the cervix.

Methods: In a quasi-experimental study, 70 pregnant women with a gestational age between 14 and 28 weeks and unfavorable cervix, requiring induction of labor were randomly allocated into to 2 groups. For each mother, digital cervical examination was performed before and at regular intervals to determine the Bishop score. One group received vaginal suppository of 3 mg dino-prostone that was re-administered after 6 hours, if necessary. For the other group, a Foley catheter balloon was inserted in the internal os of cervix that was filled with 30 mL sterile normal saline and kept under traction. Serum oxytocin augmentation was given to both groups after 12 hours as a routine. The outcome variables including the change in cervical Bishop score, beginning of uterine contractions and complications during and after labor were assessed. Student's t test and Chi-square were used for the analyses of data.

Result: Induction to delivery time in Foley catheter group (15.0±7.7 h) was significantly (p<0.01) lower than that of PGE₂ group (20.8±5.8 h). The rate of post-partum curettage for residual placenta or post-partum infections which required hospitalization and other complications were similar in both groups. The time saved for cervical ripening in Foley catheter group was 6.4±4.2 h.

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Keywords • Prostaglandins, E • reproductive medicine • labor • foley catheter • cervical ripening.

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Introduction

While the overwhelming majority of pregnancies terminate safely, in some instances, however, early termination of pregnancy becomes desirable.^{1,2}

Termination of pregnancy by medical or surgical methods, especially in the presence of unfavorable cervix may lead to additional difficulties and complications. Cervical ripening, before induction of labor, is needed to increase the success of labor induction, to reduce complications and to diminish the rate of cesarean section and duration of labor.^{2-5,6}

Prostaglandin E₂ (PGE₂) suppositories, as a medical method, and Foley catheter balloon inflated at the cervical internal os, as a mechanical method, can be used in ripening of the cervix.⁶⁻¹⁰ There are only a few clinical studies comparing the efficacies as well as the complication rates of the aforementioned techniques. Given the diversity of results by different investigators on conventional methods of cervical ripening before induction of labor, we conducted this study to determine and compare the efficacy, induction to delivery time and complication rates of two earlier-mentioned techniques, i.e., PGE₂ suppositories and inflated Foley catheter, in pre-induction cervical ripening.

Patients and Methods

In a quasi-experimental study conducted between the years 2000 and 2001 at the Emam Reza Hospital in Mashhad, 70 women with a gestational age of 14-28 weeks and unfavorable cervix (Bishop score ≤ 4)⁷ requiring induction of labor, were randomly allocated into two groups. Subjects with asthma, epilepsy, heart diseases, diabetes, severe hypertension, placenta previa, uterine bleeding, uterine contractions, mal-presentation and uterine cicatrices were excluded from the study.

For each mother, a digital cervical examination

was performed to determine the Bishop score. A skilled obstetrician performed all examinations. One group received vaginal suppository containing 3 mg dino-prostone inserted in the posterior fornix and re-administered after 6 hours, if necessary.

For the other group, a G16 Foley catheter balloon was inserted in the cervical internal os that was filled with 30 ml sterile normal saline and kept under mild traction by a 500 g scale stone.

Oxytocin augmentation was routinely given to both groups after 12 hours, i.e., 15 drops/min of 20 U oxytocin in 1000 ml Ringer's solution. The outcome variables including the change in cervical Bishop score, beginning of uterine contractions and complications during and after labor were assessed. Personal characteristics and other information were gathered and recorded in a questionnaire. Student's t test was used for normally-distributed, and Chi-square test was used for categorical data. Statistical tests with $p < 0.05$ were considered significant.

Results

Table 1 shows the demographic characteristics of participants. Considering the parameters studied and using Student's t test, no significant difference was observed between the two groups. No participant failed to complete the protocol or requested to be withdrawn from the study.

Table 2 shows a summary of parameters measured during labor and after delivery. The two interventions used, resulted in successful onset of uterine activity in all but seven cases. Abruption of placenta occurred in two patients (one in each group). Nine patients (5 from Foley catheter and 4 from PGE₂ group) underwent hysterotomy. Induction to delivery time varied from 2 to 36 hours and was significantly ($p < 0.01$) shorter in Foley catheter group compared to PGE₂ group. In 15 patients, residuals of placenta were detected by sonography. They underwent curettage, however, no significant difference was observed between rates of

Variables	Mean \pm SD	
	Foley catheter (n=37)	PGE ₂ (n=33)
Maternal age (yr)	28.1 \pm 7	26.2 \pm 5.4
Gestational age (wk)	22.5 \pm 5.2	21.7 \pm 5.2
Number of pregnancies	2.9 \pm 1.8	3.06 \pm 1.7
Number of deliveries	1.36 \pm 1.5	1.5 \pm 1.4
Interval between two latest pregnancies (m)	32.8 \pm 17.1	23.2 \pm 15.7

Comparing the efficacy of PGE₂ suppository and cervical Foley catheter in pre-induction ripening of cervix

Table 2: Labor and delivery characteristics			
Groups Variables	Foley catheter (n=37)	Prostaglandin E ₂ (n=33)	p Value
Primary Bishop Score	2.2±.7	2.03±0.9	NS
Secondary Bishop Score	6.6±.5	6.1±0.9	NS
Bishop score changes	4.4±.4	4.02±0.5	NS
Induction-to-delivery interval	15.0±7.7	20.8±5.8	<0.01
Vaginal delivery	32(91%)	29(82%)	NS
Hysterotomy	5(14%)	4(11%)	NS
Post-partum curettage	7(20%)	8(23%)	NS

NS = Not Significant

post-partum curettage in the two groups (Table 2).

Other complications observed included nausea and vomiting in 1 case, diarrhea in another one, headache in 1, and hot flashes (<37.8 °C) in 7 cases of PGE₂ group. Post-partum infectious complications were similar in both groups; two cases of PGE₂ and three of Foley catheter group developed post-partum infection. They were hospitalized and treated accordingly; all these cases underwent hysterotomy.

The mean±SD time between insertion and reescape of Foley catheter from the cervix was 6.4±4.2 hours. In two patients, the catheter did not escape. In these cases, the catheters were removed manually after 12 hours. Twenty-four (75%) of 33 patients in PGE₂ group required two PGE₂ suppositories to ripen the cervix.

Discussion

We found that intracervical insertion of inflated Foley catheter balloon or intravaginal administration of suppository of PGE₂ have excellent efficacy with minimal side effects and can promote the cervical Bishop score and prepare the cervix for induction of labor by oxytocin. The induction to delivery interval in Foley catheter group was significantly shorter than PGE₂ group. The rate of failure was also equal in both groups.

Prostaglandins E and F in the form of oral, intra- and extra-amniotic, intra-muscular, intra-myometrial as well as vaginal and cervical jelly are suggested for induction of labor and abortion.^{2,6,7,11-21} Vaginal suppositories (Dino-prostone) are preferred by some investigators, since its absorption is lower than PGE₂ jelly (3 mg/h) and the systemic complications (nausea, vomiting, and diarrhea) are less severe.⁷

Onge in 1995, found no difference between the efficacy of intra-cervical Foley catheter and pro-

staglandin vaginal jelly, and also between their side effects when were used in cervical ripening.²²

Sherman et al. (1996) suggested that inflated Foley catheter balloon is more effective and has lower side effects compared to other mechanical and medical methods of cervical ripening.²³ In a study conducted by Atlas et al. (1998), the use of combined methods of Foley catheter and cervical PGE₂ jelly in comparison to two doses of cervical prostaglandin PGE₂ jelly, resulted in higher cervical Bishop score and lower rate of induction failure. In this study complications such as cesarean section, uterine hyper-stimulation and post-partum infection were similar in the two groups.¹⁰

In another study, Sciscione et al used Foley catheter for ripening of cervix before induction of labor by oxytocin, and had excellent efficacy and minimal side effects.²⁴

Considering our findings, the use of intra-cervical Foley catheter in ripening and termination of pregnancy is as effective as intravaginal administration of PGE₂. It can shorten the induction-to-delivery interval with minimal side effects. Foley catheter is easy to use, and is more accessible at lower cost, therefore, as a mechanical method, can be used instead of prostaglandin in ripening of unfavorable cervixes.

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