A Randomized Controlled Trial of Foley Catheter, Extra-Amniotic Saline Infusion and Prostaglandin E2 Suppository for Labor Induction

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Abstract

Objective: The aim of this study is to further compare the efficacy of PGE2 suppository, the intracervical foley catheter and extra-amniotic saline infusion in nulliparous women referred for labor induction.

Materials and methods: totally 368 nulliparous women with a Bishop score ≤ 4 with singleton gestation, vertex presentation and intact membrane referred for labor induction were randomly assigned to 3 groups; Foley catheter alone, Extra-amniotic saline infusion (EASI) and PGE2 suppository. All women received concurrent dilute oxytocine infusion. The change in the Bishop Score, labor progress, various labor endpoints and outcomes of labor were assessed.

Results: From 363 women studied after exclusion of 5, 119 were assigned to EASI, 121 to Foley and 118 to PGE2. Patients' demographics did not differ significantly between three groups nor did indication for induction (P=0.0001).The EASI group had a significant improvement in Bishop Score 6 hours after induction. The mean time to active phase was 357±135min for EASI,457±178 for Foley and 609±238 min for PGE2 group respectively (P<0.05).rate of spontaneous rupture of membranes was higher in the EASI group (P=0.0001) and the mean time from the start of induction up to spontaneous rupture of membranes in the EASI group was shorter than other group(P<0.05).The mean time to vaginal delivery was 14.8±6.1 in EASI group,11.4±4.8 in Foley and 18.9±6.4 in PGE2 group(P<0.05).there were no differences in Apgar scores, mean neonatal birth weight and neonatal morbidity.

Conclusion: Our study showed that pre-induction cervical ripening by EASI with concurrent oxytocin is better than Foley and PGE2 in Bishop score and various labor end point and outcomes.

Keywords: labor induction, Foley catheter, Extra-amniotic saline infusion, PGE2

Introduction

Induction of labor can be defined as the artificial initiation of labor, before its spontaneous onset, for the purpose of delivery of the fetoplacental unit (1, 2). The most common reasons for induction of labor are post-term pregnancy, diabetes, maternal request and hypertensive disorders of pregnancy (2, 3). The state of the cervix before induction, as measured by Bishop Score, has been shown to be an important determinant of the success or failure of induction (4). There are two categories of artificial

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means of cervical ripening prior to labor induction: mechanical (the foley catheter balloon and laminariatents),and pharmacological (prostaglandins PGE1,PGE2 and PGF2α and estrogen). Mechanical devices dilate the cervix by accessing the fetal membrane, and pharmacological preprations cause connective tissue softening, cervical effacement, and uterine activity (5, 6). Despite the multiplicity of techniques, there is no universally accepted thus the ideal method of labor induction remains elusive (7, 8). Several studies show mechanical ripening with a Foley bulb to be at least as effective as other methods of ripening, with no increase in maternal or fetal morbidity (9-12). Some of these studies describe placing the Foley bulb beyond the internal cervical os and inflating it with sterile water (3.8m), whereas others supplement Foley bulb placement with an extra-amniotic saline infusion through the catheter (4).

On the other hand prostaglandins are effective agent for cervical ripening (13-14). Prostaglandins in general, specially the PGE, have been extensively studied for clinical use, for cervical ripening and labor induction (15, 16).

The aim of this study is to further compare the efficacy of PGE2 suppository, the intracervical foley catheter and extra-amniotic saline infusion in nulliparous women referred for labor induction.

Materials and methods

This study was conducted in the maternity clinic of Alzahra hospital, Guilan, Iran. The ethical committee of the Guilan University of Medical Sciences approved the study. patient admitted to hospital for delivery between March 2007 to novamber 2009 .

All women were evaluated for eligibility for this trial by resident physicians. Pregnant women were eligible for enrollment if they were: primiparous; between 37 and 42 weeks gestation; had a singleton pregnancy with the fetus in vertex presentation; an unfavorable cervix, defined as a Bishop score ≤ 4; intact membranes and reassuring fetal heart rate tracing; or had no more than two painful contractions in a 20 minutes period. Women were excluded if there was significant vaginal bleeding, evidence of spontaneous labor, known contraindications to labor induction, fetal heart rate abnormalities, and failure to successfully placement of the Foley catheter. Written informed consent was taken for participation in the study and after undergoing vaginal examination to determine the Bishop score, the patients were divided randomly into three groups by numbered opaque envelopes: Foley catheter group alone (Foley), extra-amniotic saline infusion (EASI) and prostaglandin E2 (PGE2) group. In addition, standard oxytocin infusion was begun immediately for labor and delivery protocol.

After patient selection and randomization, the Foley catheter was inserted for all patients in Foley and EASI groups. In the dorsal lithotomy position, under direct observation, a 22- gauge Foley catheter was inserted aseptically through the internal os of the cervical canal into the extra-amniotic space. The catheter balloon was filled with 30 ml of normal saline and lodged in the lower uterine segment. The catheter was pulled back against the internal os and went under traction using a bag containing 500 ml normal saline. Then normal saline was infused through the catheter port at 40 ml per hour into the extra- amniotic space in EASI group. After catheter placement , intravenous infusion of oxytocin in normal saline was started at an initial dose of 6 mu/min , which increased at 20- minute intervals by 6 mu/min to a maximum dose of 42 mu/min or until adequate labor was established. Oxytocin was continued after spontaneous expulsion of the Foley catheter until adequate labor was established. Each subject had a sterile vaginal examination at 6, 12, 18 and 24 hours or when clinically indicated. Whenever possible, serial assessments were made by the same individual. The catheter was removed 12 hours after insertion, unless it had been expelled spontaneously or removed after spontaneous rupture of membranes.

Patient randomized to the intracervical suppository received PGE2 0.5 mg intracervicaly (suppository Dinoprostone 5γphramucia NV-SA puurs Belgium). The patients remained recumbent for at least 30 minutes after application. a repeat intracervical suppository (for a maximum of 3 doses) was placed at 6 hours if spontaneous labor or rupture of membranes had not occurred. Before administration of the next dose, contraction frequency was evaluated. If there were three or more contractions in 10 minutes, the woman was observed for 1 hour for evidence of cervical dilation (at least 1 cm per hour). If labor was progressing, the next dose was withheld.

Labor was augmented with oxytocin in the active phase if progress was arrested for longer than 2 hours.

For the purpose of this study failed induction was defined as labor arrest before achieving at least 4 cm cervical dilatation. Failure to progress was defined as secondary arrest of labor at or after 4 cm cervical dilation despite adequate uterine contractions for a

minimum of 2 hours. The active phase was defined as complete cervical effacement and dilatation of at least 4 cm. Successful induction was defined as occurrence of normal vaginal delivery within 24 hours after initiation of induction.

An abnormal FHR pattern was defined as the occurrence of prolonged fetal bradycardia, recurrent, late or variable decelerations. tachysystole was defined as six or more contractions in a 10-minute period. Hyperstimulation was defined as the presence of tachysystole resulting in abnormal FHR patterns. Hyperstimulatin was managed at the discretion of the attending physician.

Our primary outcome was the interval between the start of induction to the active phase. Secondary outcomes include the rate of induction success, the duration of labor, the incidence of cesarean delivery, rate of spontaneous rupture of membranes before the active phase and interval to this event, cesarean rate for failed induction, neonatal Apgar score at 1 and 5 minutes and other outcomes such as maternal and neonatal complications.

The remainder of the induction process proceeded according to the standard management of labor employed in labor and delivery. Single dose prophylactic antibiotic was administered to all patients after 12 hours from the onset of induction.

In all groups, amniotomy was done in the absence of spontaneous rupture of membranes in these conditions: active phase of labor, non- reassuring FHR, secondary arrest of labor. Pain management was determined by the primary care providers and patients.

Statistical analyses

Statistical analyses were performed using SAS release 6.11 for personal computers (SAS Institute, Cary, NC).Normally distributed continuous data were analyzed with the Student t-test, and non-normally distributed data were compared with the Wilcoxon rank-sum test $\chi 2$ and Fisher exact test were used to compare categorical data. Statistical significances were defined as $P < 0.05$.

Results

A total of 363 women with gestational ages of 37- 42 weeks were enrolled in this study. Five labor were excluded (3 cases from the PGE2 group and 2 cases from the EASI) in one cases the catheter was not successfully placed because the patient was not intolerance of the procedure. In another patient foley catheter insertion was failed and thus, suppository was used. Other patients had bleeding after placing the foley catheter, one patient had placental abruption 2 hours after receiving PGE2 and underwent caesarean, and one patient had score of 7 on PGE2 suppository after 24 hours and labor was induced. Of the remaining 358 pregnant women, 121 were assigned to the Foley group, 119 to the extra-amniotic saline infusion (EASI) group and 118 to the PGE2 group. Patient demographics did not differ significantly between the three group (maternal age and gestational age), nor did indication for induction (abnormal fetal testing, post- term pregnancy, preeclampsia, oligohydramnios, IUGR and GDM) and the other factors that might influence outcome interest (Table1).

All patients were primiparous. The most common causes for pregnancy termination in all groups were abnormal fetal testing (41 in EASI group, 44 in Foley group and 39 in PGE2 group).

Table 1: Characteristics of patients

Variables	Salin infusion (n=119)	Foley (n=121)	PGE2 (n=118)	p-value
Maternal age (year)	23.8±3	24.1±2	22.5±4	0.06
Mean gestational age (week)	39.7±0.9	39.1±1.4	38.9±1.9	0.32
Indication of induction				
Abnormal fetal wellbeing test	41	44	39	0.86
Post term pregnancy	22	19	20	0.84
Hypertensive disorders	20	17	19	0.81
Oligohydramniosis	15	21	17	0.52
Intrauterine growth retardation	10	9	11	0.87
Gestational diabetes	2	3	5	0.87
Others	9	8	7	0.88

From a total of 118 patients 61 women who received PGE2 required only one dose, but 39 women needed two doses.

In the PGE2 group, 5 Patient developed maternal side effect including nausea, vomiting, and diarrhea.

There were no significant differences in the mean initial Bishop scores between the three groups (Table 2). In all groups a considerable improvement occurred in Bishop score 6 hours after initiation of induction, but this progress in the EASI group was greater than the Foley and PGE2 group (P <0.0001). The mean (±SD) time from initiation of induction to active phase of labor in the EASI Group was shorter (EASI 357±135 hours, foley group 457±178 hours and PGE2 609±238 hours P <0.05). The incidence of tachy-systole in all groups was high, but it was higher in the EASI group.

29 labors were complicated by hyperstimulation that was treated by discontinuing the oxytocin. No patient required cesarean for hyperstimulation. Rate of spontaneous rupture of membranes was higher in the EASI group (P=0.0001) and the mean time (±SD) from the start of induction up to spontaneous rupture of membranes in the EASI group was shorter than in the Foley and PGE2 groups (p<0.05).

Table 3 illustrates interval times from beginning of cervical ripening to various labor end points, including cesarean rate, cesarean indications, mean interval to vaginal delivery and mean interval to cesarean in the three groups.

Forty four patients required amniotomy in the active phase of labor. The incidence of meconium passage was not significantly different in the three groups. There were no significant differences in the cesarean rates and indications of cesarean between all groups. The most common cause of cesarean in the three groups was FHR abnormalities (15 cases in EASI group, 12 in Foley group and 21 in PGE2 group). The cesarean rate due to failure to progress was similar in both groups (EASI 7; foley 7, PGE2 10 cases). Only 4 patient in the EASI group, 8 in the Foley group and 8 in the PGE2 group underwent cesarean due to failed induction. The mean interval (±SD) from the onset of induction to vaginal delivery in the Foley group was significantly lower than in the EASI and PGE2 groups (vaginal delivery in EASI group: 14.8± 6.1 ,Foley group: 11.4±4.8 and PGE2 group: 18.9±6.4, p<0.05. cesarean in EASI group: 14.8±2.6, Foley: 12.6±2.5 and PGE2: 20±9.8, p<0.05).

Table 2: labor profiles

Variables	Salin infusion (n=119)	Foley (n=121)	PGE2 (n=118)	p-value
Initial Bishop score	3.6±1.3	3.1±1.9	3.3±1.5	0.12
Bishop score ≥ 7 hours after induction initiation	69 (58%)	35 (29%)	25 (21%)	0.0001
Duration before active phase (Mean± SD) (minute)	357±135	457±178	609±238	0.04
Abnormal FHR	37	39	30	0.46
Hyperstimulation	12	8	9	0.599
Tachysystole	90	17	28	0.05
Spontaneous rupture of membranes	96 (80.6%)	76 (62.8%)	58 (49.1%)	0.0001
Interval to rupture 0f membranes (hour)	5.2±2.8	8.5±3.5	9.8±4.3	0.01

Table 3: Delivery outcome

Variables	Salin infusion (n=119)	Foley (n=121)	PGE2 (n=118)	p-value
Cesarean delivery	32 (26.8%)	30 (24.7%)	41 (34.7%)	0.20
Indications of delivery				
FHR abnormalities	15	12	21	0.19
Failure to progress	7	7	10	0.64
Meconium passage	6	3	2	0.29
Failed induction	4	8	8	0.43
Mean time to vaginal delivery (minute)	14.8±6.1	11.4±4.8	18.9±6.4	p<0.05
Mean time to cesarean (minute)	14.8±2.6	12.6±2.5	20±9.8	p<0.05

There were significant differences in unfavorable maternal and neonatal outcomes such as chorioamnionitis (p=0.039); postpartum metritis (p=0.881) and no significant differences number of APGAR scores less than 7 at 1 and 5 minutes; mean neonatal birth weight and admission to NICU between the three groups (Table 4).

Spontaneous rupture of membranes occurred in 96 patients (80.6 %) from the EASI group , 76 (62.8 %) from the Foley group and 58 Patient (49.1 %) from the PGE2 group (p=0.0001) and time to rupture of membranes occurred 3.3 hours earlier in the EASI group compared with the Foley group (5.2±2.8 in EASI arm versus 8.5±3.5 in Foley arm).Patients with artificial rupture of membranes were delivered vaginally after 251±104 minute in the EASI group, 993±215 minutes in the Foley group and 1258±236 in the PGE2 group (p<0.05) (Table 5).

Discussion

One of the common practices of modern obstetrical care is to labor induction when fetal and/or maternal complications arise (17).

Cervical ripening and induction of labor are debatable issues (18). Although numerous studies have compared ripening methods, no consensus exists on which is best. An ideal ripening agent would be effective over a reasonably short time; it would cause minimal uterine activity during its period of effect; it would be reversible and not compromise other procedures that may follow; it would have no adverse effects on fetus or mother; it would be easy to administer; and–which would be welcome in resource-poor countries–it would be inexpensive to use (19-21).

In this study the most common reason for labor induction were abnormal antepartam fetal testing (n=124).

The rate of tachysystol in the EASI group was greater than in the dinoprostone group (p<….), which is similar to some other studies (11, 22).

The results of our study showed that the extra-amniotic saline infusion method compared with Foley catheter had greater success regarding cervical ripening, labor induction, shorter time to delivery and shorter time to active phase of labor in nulliparous women with an unfavorable cervical examination without increasing the cesarean rate, cesarean rate due to fetal intolerance to labor or failure to progress (5).

The overall cesarean delivery rate in this study were similar in the three groups. this agree with results reported in other trials (20, 23).

Table 4: Maternal and neonatal outcome

Variables	Salin infusion (n=119)	Foley (n=121)	PGE2 (n=118)	p-value
Chorioamnionitis	8	10	19	0.039
Postpartum metritis	9	8	7	0.881
Neonatal birth way (gr)	3191±262	3276±460	3194±348	<0.05
1 minute Agar score ≤ 7	15	10	12	0.29
5 minute Agar score ≤ 7	1	2	0	0.96
Admission to NICU	9	10	11	0.88
Neonatal stay (day)	2	2	2	1.0

Table 5: Mean duration (± SD) before active phase and delivery: spontaneous versus artificial rupture of membrane

Variables	Salin infusion (n=119)	Foley (n=121)	PGE2 (n=118)	p-value
Artificial rupture of membranes				
Time to active phase (minute)	218±120	476±207	511±127	p<0.05
Time to delivery (minute)	251±104	993±215	1258±236	p<0.05
Spontaneous rupture of membranes				
Time to active phase (minute)	566±261	830±268	998±103	p<0.05
Time to delivery (minute)	357±135	457±178	738±112	p<0.05

Distribution of indications leading to cesarean delivery was similar in both groups, indicating further similarities between the three methods. A similar distribution of these indications is seen in other published studies (6, 24, 25). study showed no differences in vaginal delivery rates between foley catheter and prostaglandin use.

As was expected, bishop scores improved significantly in both groups after treatment. The PG intervention took a longer time than the Foley catheter to ripen the cervix, indicating a more favorable outcome with the Foley catheter. A shorter ripening time and induction time with Foley catheter has also been reported in several studies (19, 20, 24), indicating an overall satisfaction for this method among patients and physicians.

The overall rate of cesarean in this study was 28.6%, which is higher than in other studies (8, 25). We believe that the reason for this increase may be the characteristics of the assigned population, being all nulliparous patients. Nulliparity is one of the most important factors known to increase cesarean rate due to failure to progress (26, 27) in a study by bortolus et al. (27), 250 women with bishop score less than 4 underwent induction by PGE2 suppository. Nulliparity was the most important factor to cause failed induction (19% in comparison to 3% in multiparous women) (28, 29).

Neonatal outcome in this study (neonatal weigh, 1- and 5- min APGAR scores, and length of hospital stay) indicate that three methods are safe for neonates, and that no major differences are seen in neonates born to women delivered with each method. This supports similar reports from other studies (20, 25).

PGE2 increases the risk of chorioamnionitis compared with induction of labor with other methods. In this study, the risk of chorioamnionitis was 16.1% in the PGE2 group, 8.2% In the Foley group and 6.7% in the EASI group which were similar to the other studies (30, 31).

In a review of 11 reported studies, it has been suggested that ripening efficacy by catheter balloon is similar to, or better than, other methods (32).

One important concern was the possibility of causing ascending infection with the Foley catheter and extra-amniotic saline infusion. However, we found no significant complication related to the use of this method (7).

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