

Prostaglandin E2 versus Foley Catheter Balloon for Induction of Labor at Term: A Randomized Controlled Study

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ABSTRACT

Objective: The aim of this study is to evaluate the efficacy, safety and side effects of intracervical Foley catheter balloon in comparison with intra vaginal prostaglandin pessaries in preinduction cervical ripening at term.

Methods: This randomized prospective study was conducted in the maternity department at King Hussein Medical Centre and Prince Ali Bin Al-Hussein Hospital between July 2009 and July 2010. Four hundred and fourteen women who required induction of labor, with a Bishop score of less than or equal to 5 and met the inclusion criteria, were randomized into two groups: 204 women received prostaglandin E2 vaginal tablets (group I) and 210 women had an intracervical Foley catheter inserted, and the balloon inflated with 60 ml N/Saline (Group II). The outcome measures were: mode of delivery, time interval between induction to delivery and maternal and neonatal adverse reactions.

Results: Age, parity and indications for induction of labor, were similar in both groups. In Group I, 63% achieved normal vaginal delivery compared to 61% in Group II ($p= 0.8$). Cesarean section rate was 34% in both groups. The rest had instrumental delivery. The time interval between induction to delivery was longer in the Foley catheter group than PGE2, but not statistically significant (mean 22.6 h vs. 21.4 h; $P= 0.3101$). The rate of oxytocin administration was more in Foley catheter group than Prostaglandin E2 (78.6% vs.65.7%; $P= 0.018$). Uterine hyper stimulation was more in PGE2 group than Foley catheter 6 (3%) vs.1 (0.5%); $P= 0.0013$). The Apgar scores, neonatal birth weight and admission to neonatal intensive care unit showed no difference between the two groups.

Conclusion: PGE2 vaginal tablets and Foley catheter are comparable in efficacy for induction of labor in women at term. However, Foley catheter has the advantage of being safe, simple, reversible and associated with fewer side effects.

Key words: Foley catheter, Induction of labor, Mode of delivery, Prostaglandin E2,

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Introduction

Induction of labor (IOL) is a common obstetric intervention. It involves the use of mechanical or pharmacological methods in order to achieve cervical ripening, regular uterine contractions, cervical dilatation and subsequent delivery.⁽¹⁾

Generally, IOL is indicated when the benefits of delivery to the mother or fetus outweigh the potential risks of continuing the pregnancy.⁽¹⁾ The indications for IOL are either maternal, fetal or both. In pre-eclampsia, diabetes mellitus and various other medical disorders, IOL aims to

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reduce maternal morbidity. IOL for fetal reasons aims to reduce fetal or neonatal morbidity and mortality. Common fetal indications include: post date pregnancy, intra uterine growth restriction, oligohydramnios, presumed fetal distress and premature rupture of membranes at term.

Induction of labor is performed in about 20% of pregnancies.⁽²⁾ The failure of induction, which usually necessitates Cesarean section, occurs in 20% of cases.⁽³⁾ Another important complication of IOL is uterine hyper stimulation, which is associated with both maternal and perinatal morbidity and mortality.⁽⁴⁾

The success of IOL depends on the pre-induction condition of the cervix. The method most commonly used to identify readiness (ripeness) for onset of labor is the Bishop score which includes quantitative measures of consistency, and dilatation of the cervix, and station and position of the presenting part.⁽⁵⁾

In the course of a normal pregnancy, softening and dilation of the cervix is the result of complex of biochemical reactions including, decreased collagen and glycosaminoglycan concentrations as well as increased water content which results in a cervix favorable for normal or induced labor. In a normal pregnancy, these changes accelerate towards the end of the pregnancy and pave the way for the start of spontaneous labor. When this process fails at term, or delivery is needed at earlier stage, the cervix must be ripened through artificial means.⁽⁶⁾ When the cervix is ripe, induction of labor is done by artificial rupture of membranes (ARM) and intravenous Oxytocin. Ripening of the cervix is accomplished by various methods. Historically, laminaria tents were used to achieve ripening. Other methods include catheter balloons with or without intrauterine instillation of various agents and more recently Prostaglandins.

Synthetic prostaglandin such as prostaglandin E2 (PGE2) imitate normal physiological cervical ripening and increase the sensitivity of the uterine myometrium to Oxytocin.^(7, 8)

Systemic absorption of this agent is possible and may result in nausea, vomiting, and initiation of uterine contractions. The effect may last for prolonged periods and lead to uterine hyper tonicity, placental abruption, and uterine rupture.⁽⁹⁾

Mechanical ripening devices apply pressure on the internal so of the cervix, distending the lower uterine segment and indirectly increasing localized secretion of prostaglandin.⁽¹⁰⁾ Foley catheter is less costly than PGE2 and has fewer adverse effects, particularly in uterine hyper-stimulation. Studies have shown no increased risk of perinatal infections with the use of Foley catheter for cervical ripening.⁽¹¹⁾

The aim of this randomized prospective study is to compare the efficacy and safety of prostaglandin E2 tablets with the intracervical Foley catheter for IOL at term.

Methods

This prospective randomized controlled study was conducted at King Hussein Medical Centre and Prince Ali Bin Al-Hussein hospital. The study was approved by the Ethical Committee of the Royal Medical Services in Jordan.

Between July 2009 and July 2010, 414 consecutive women undergoing IOL at term, were randomized into two groups. Group I (n= 204) were induced by Prostaglandin E2 vaginal tablets (Prostin E2® Vaginal Tablet; Pharmacia & Upjohn, Belgium) and Group II (n= 210) by Foley catheter balloon.

The entry criteria for the study were women aged 15 years or more, pregnancy at term with singleton live fetus in vertex presentation, intact membranes and Bishop score <6.

The exclusion criteria were: Previous Cesarean Section or history of other uterine surgery, history of ante partum hemorrhage, non vertex presentation, twin pregnancy, cephalo pelvic disproportion, acute fetal distress revealed by a non stress test prior to induction, signs of infection, ruptured membranes, estimated fetal weight >4300, or known allergy to Prostaglandin.

The eligible women who fulfilled the entry criteria and consented to the study were assigned randomly to one of the two induction methods. Randomization was done by a computer generated list of random numbers.

The primary outcome measures were mode of delivery and the time interval between the start of induction and delivery. Secondary outcome measures were Oxytocin requirement, the indications for cesarean section and adverse neonatal and maternal reactions to the cervical ripening agents.

Participants in the study were admitted to the labor ward and 30 minutes admission Cardiotocogram (CTG) was performed and a Bishop score was assessed by an obstetrician. The patients were examined every 4 hours to assess the progress of the induction process.

In Group I, Prostaglandin E2 (Prostin ® Vaginal Tablet 3 mg; Pharmacia & Upjohn) was inserted in the posterior vaginal fornix. If contractions had not started or the patient did not need analgesia 6 hours later, a second dose of 3 mg was administered. External electronic fetal heart rate monitoring was recorded before and for 40 minutes after each PGE2 insertion. Artificial rupture of membranes was performed and oxytocin infusion was administered if labor did not commence after two doses. Oxytocin was withheld for six hours following administration of vaginal prostaglandins, in order to minimize uterine hyper tonus.

In the second group a Foley catheter was inserted through the cervical canal. In lithotomy position, the cervix was exposed with sterile speculum (Cusco) cleansed with povidone iodine solution (Betadine®; SSL) and a 22- 24 Foley catheter was inserted through the external cervical os with a sponge holding forceps. Thereafter, the balloon was inflated above the internal os with 50-60 ml of normal saline. The Foley catheter was taped to the women's inner thigh to maintain traction. The procedure was covered by prophylactic Cefoxitin (Mefoxin®; MSD) 1 g IV which was continued 8-hourly until expulsion of the catheter. The catheter was removed after 24 hours if it did not fall out spontaneously. External electronic fetal heart rate monitoring was recorded before and for 40 minutes after Foley catheter insertion. Artificial rupture of membranes was tried and oxytocin infusion was administered if labour did not commence after expulsion or removal of the catheter.

Progress of labor was managed according to local labor ward protocols. Artificial rupture of membranes was performed as soon as cervical dilatation reached or exceeded 3cm. Oxytocin was started if there was unsatisfactory progress of labor or inadequate uterine activity (<3 contractions /10 minutes). The oxytocin infusion was administered according to labor ward protocol. Pethidine was given intramuscularly for

pain relief on maternal request. Entonox and Epidural analgesia are not available in the two hospitals where the study was conducted.

When uterine contractions became established cardiotocography monitoring was continued until delivery. 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.⁽¹²⁾ Fetal heart rate was considered abnormal if there was persistent reduced baseline variability, tachycardia, late decelerations or variable decelerations.

Failed induction of labor was defined as inability to rupture the membranes after two doses of PGE2 or 24 hours of Foley catheter insertion or when the cervix does not dilate beyond 3 centimeters despite adequate and appropriate oxytocic stimulation over 8 hours in a nullipara and 4 hours in a multipara.

We did not use cross over between the two methods in this study, if the first method used primarily for induction of labor failed. We also did not use a rest period and restart again in women who had failed induction.

Statistical analysis to compare the groups was performed using the Student's T-test for continuous variables, and Chi-square test for categorical variables. Statistical version 9 (Statsoft INC, Tulsa USA) was used for the analysis.

Results

The baseline characteristics (Table I) and the indications for IOL (Table II) were comparable in both groups. The commonest indication for IOL was post date pregnancy (58.3% in Group I and 61.4% in group II).

There were no significant differences in the mode of delivery between the two study groups (63% in Group I and 61% in Group II had normal vaginal delivery). The cesarean section rate was 34% in both groups. However, more cesarean sections were performed for fetal distress in group 1 (60% vs.44%), but this did not reach statistical significance ($P = 0.25$).

Instrumental delivery was required in 2.5% and 4.8% respectively. There were no significant differences between the two groups with respect to the mean time interval between

Table I: Base line characteristics of the two study groups

	PGE2 N=204	Foley catheter N=210	P-value
Age (years, mean(SD))	26(6.3)	26.1(5.5)	0.8634
Parity (mean(SD))	1.3(1.5)	1.4(1.7)	0.5265
Nulliparae (n(%))	103(50.5)	92(43.8)	0.4285
Gestational age (weeks, mean(SD))	40.3(1.7)	40.5(1.6)	0.2183
(weeks, median(range))	41(37-42)	41(37-42)	
Bishop score prior to induction (mean(SD))	2.4(1.3)	2.3(1.4)	0.4521
(median(range))	2(1-5)	2(0-5)	

Table II. Indication for induction of labor of the two study groups

	PGE2 N=204	Foley catheter N=210	P-value
Post date	119(58.3%)	129(61.4%)	0.7129
Pre-eclampsia	9(4.4%)	10(4.7%)	0.2845
Fetal growth restriction(IUGR)	5(2.4%)	7(3.3%)	0.0997
Reduced liquor	26(12.7%)	22(10.5%)	0.8302
Reduced fetal movement	23(11.3%)	24(11.4%)	0.6533
Maternal minor complaints*	6(2.9%)	5(2.4%)	0.0678
Others +	16(7.8%)	13(6.2%)	0.5750

*Generally feeling unwell, pruritis, nausea and vomiting, abdominal discomfort.

+Non reactive CTG, Infertility, Bad obstetric history

induction and delivery (21.4 and 22.6 hours for Group I and Group II, respectively; $P=0.3101$) as well as the mean time interval between induction and artificial rupture of the membranes (ARM) (10.16 and 9.61 hours respectively; $P=0.3333$). The rate of failed induction was also similar (10% and 8.3%, respectively; $P=0.3919$) (Table III).

There were significant differences between the two groups with regard to oxytocin augmentation requirement (65.7% and 78.6% for Group I and Group II, respectively; $P=0.0181$) as well as uterine hyper stimulation, which was more frequent in Group 1 (3% and 0.5%, respectively; $P=0.0013$). (Table III).

Foley catheter was inserted successfully in all patients. However, three women in the Foley catheter group developed mild bleeding at the time of insertion of the catheter which stopped after few minutes without intervention. There were no significant differences in requirement for analgesia between the groups. (Table III).

Maternal fever occurred in the peripartum period in 7% and 6% of cases respectively. However, this was mild, and no severe infective morbidity was encountered. Neonatal outcomes were similar and are illustrated in Table IV.

Discussion

The results of this study have demonstrated no difference in the mode of delivery between the two study groups. Cesarean section rate was similar in both groups, but the percentage of cesarean section due to fetal distress was more in women who received PGE2. This may be explained by the pharmacological effect of Prostaglandins on uterine activity which on occasions leads to uterine hyper stimulation. These results are consistent with previous studies^(10,13) but differ with other studies which concluded that the catheter has a higher efficacy expressed as a lower cesarean section rate.^(14,15)

Both groups were comparable with regard to induction to delivery interval. The latter was found to be longer in the Foley catheter group than PGE2 in one study.⁽¹⁰⁾ However, another study reported more efficacy of the Foley catheter expressed as a lower induction to delivery interval.⁽¹⁶⁾

Both the proportion of women requiring oxytocin and the duration of oxytocin were higher in the Foley catheter group. This finding is similar to other studies which showed that Foley catheter is less efficient than PGE2 in inducing regular uterine contractions.^(17,18)

Table III: Delivery outcome

	PGE2 N=204	Foly catheter N=210	P-value
Mode of delivery			
Normal vaginal delivery	129(63.2%)	123(60.9%)	0.8055
Instrumental delivery	5(2.5%)	10(4.8%)	0.2386
Cesarean section	70(34.3%)	72(34%)	0.8892
Indication for cesarean section			
Fetal distress	42(60%)	32(44%)	0.2580
Failure to progress	15(21.4%)	27(37.5%)	0.4665
Failed induction	7 (10%)	6(8.3%)	0.3919
Maternal distress	2(2.8%)	4(5.5%)	0.0551
Others*	4(5.5%)	3(4.2%)	0.0983
Induction to delivery(h)			
Mean(SD)	21.4(11.6)	22.6(12.4)	0.3101
Induction to ARM(h)			
Mean (SD)	10.16 (6.01)	9.61(5.54)	0.3333
Median (range)	8 (3-26)	9 (2-24)	
Use of Oxytocin n (%)	134(65.7%)	165(78.6%)	0.0181
Duration of Oxytocin(h)			
Mean(SD)	2.24(1.2)	4.97(3.94)	0.0001
Median(range)	2(1-6)	4(1-24)	
Use of analgesia (Pethidine) n (%)	170(83.3%)	162(77.2%)	0.2079
Maternal clinical infection	14(7%)	12(6%)	0.4884
Uterine hyperstimulation n (%)	6(3%)	1(0.5%)	0.0013
Minor complaints n (%) ⁺	16(7.8%)	3(1.4%)	0.3975

*Hand prolapsed, unstable lie and failed vacuum

+Nausea, vomiting, diarrhea

Table IV: Neonatal outcome

	PGE2 group	Foley group	P- value
Birth weight (mean(SD))	3463 (531)	3354 (661)	0.0655
Apgar score at 5 minutes	9.2	9.5	0.1315
Admission to NICU (n (%))*	9 (4.4%)	6 (2.8%)	0.2203

* Admission to NICU was due to birth trauma, asphyxia, jaundice, growth restriction and others.

The use of PGE2 in this study was associated with an increased rate of uterine hyperstimulation compared with the Foley catheter group (3% vs.0.5%). These findings are compatible with other studies.⁽¹⁹⁾

In our study it is shown that Foley catheter is at least as effective as vaginal prostaglandin PGE2 for pre induction cervical ripening. It is safe and well tolerated by most patients. Side effects, such as intrapartum or postpartum fever and vaginal bleeding after insertion were few. The rate of febrile morbidity in this study was equal in both groups, and similar to other studies which mentioned that pyrexia during labor may occur in less than 10% of the cases.⁽²⁰⁾ The low rate of febrile morbidity may be due to insertion of the cervical Foley catheter under aseptic conditions, in addition to the use of prophylactic antibiotics. In most studies, no prophylactic antibiotics were used. However, in our study the catheter was left in for a maximum of 24 hours twice the time

described in previous studies. For this reason prophylactic antibiotics were administered. The risk of side effects, mainly hypersensitivity reactions is a potential problem. However, no such reactions occurred in our study. Other infrequent side effects of the Foley catheter are rupture of the membranes and umbilical cord prolapse which may be due to displacement of the presenting part.⁽²⁰⁾

Side effects of PGE2 include: nausea, vomiting, diarrhea which occur in 30% of patients,⁽¹⁹⁾ and uterine hyper tonicity (0-12%).⁽¹⁹⁾ The latter may lead to uterine rupture and fetal morbidity and mortality.

Neonatal outcomes in this study including birth weight, Apgar score at five minutes and admission to neonatal intensive care unit (NICU) show that both methods of induction are safe for neonates without major differences in neonatal outcome. These results are similar to previous studies.⁽¹⁴⁾

Conclusion

Foley catheter balloon is an effective non pharmacological method for cervical ripening. It has the advantage of simplicity, reversibility, low cost and lack of systemic or serious side effects. In our study, we have shown that this method of IOL is at least as effective as the use of Prostaglandins. However, further cross over studies are required to identify benefits of these methods of IOL, when the primary method fails. This will ultimately decrease the rate of failed induction.

References

1. **James DK, Steer RPJ, Carl P, et al.** High Risk Pregnancy, Management Options. In: Luis Sanchez-Ramos, Isaac Delke. Induction of labor and pregnancy. 3rd edition. Saunders, an imprint of Elsevier 2006.
2. **RCOG.** Induction of labor .Evidence –based Clinical Guide line Number 9. London: RCOG Clinical Support Unit, 2001
3. **Crowley P.** Interventions for preventing or improving the outcome of delivery at or beyond term (Cochrane Review).The Cochrane Library. Oxford: Update Software, 2001: Issue 3
4. **Pandis GK, Papageorghiou A, Otigbah C, et al.** Randomized study of vaginal misoprostol(PGE1) and dinoprostone gel (PGE2) for induction of labor at term. *Ultrasound Obstet Gynecol* 2001; 18:629-635.
5. **Bishop EH.** Pelvic scoring for elective induction. *Obstet Gynecol* 1964; 24: 266-268.
6. **Sullivan AC, Benton LW, Roach H, et al.** Combining medical and mechanical methods of cervical ripening: does it increase the likelihood of successful induction of labor? *J Reprod Med* 1996; 11: 823-828.
7. **Kelly AJ, Kavanagh J, Thomas J.** Vaginal prostaglandin (PGE2 and PGF2a) for induction of labor at term. *Cochrane Database Syst Rev* 2003; Art. No.:CD003101
Riskin –Mashiah S, Wilkins I. Cervical ripening. *Obstet Gynecol Clin North Am* 1999; 26:243-57.
8. **Atad J, Hallak M, Auslender R, et al.** A Randomized comparison of prostaglandin E2, Oxytocin, and the Double –Balloon device in inducing labour. *Obstet Gynecol* 1996; 87:223-227
9. **Boulvian M, Kelly A, Lohse C, et al.** Mechanical methods for induction of labour. *Cochrane Database Syst Rev* 2001; Art. No.: CD001233
10. **Cromi A, Ghezzi F, Tomera S, et al.** Cervical ripening with the Foley catheter. *Int J Gynecol Obstet* 2007; 97:105-109
11. National Collaborating Center for Women’s and Children’s Health. Induction of Labor .London, UK; RCOG Press, 2008
12. **Prager M, Eneroth-Grimfors E, Edlund M, Marions L.** A randomized controlled trial of intravaginal dinoprostone, intravaginal misoprostol and transcervical balloon catheter for labor induction. *BJOG* 2008; 115: 1443-1450
13. **Niromanesh S, Mosavi-Jarrahi A, Samkhaniani F.** Intracervical Foley catheter balloon vs. prostaglandin in preinduction cervical ripening. *Int J Gynecol Obstet* 2003; 81(1): 23-27
14. **Ghezzi F, Massimo F, Raio L, et al.** Extra amniotic Foley catheter and prostaglandin E2 gel for cervical ripening at term gestation. *Eur J Obstet Gynecol Reprod Biol* 2001; 97: 183-187
15. **Gelber S, Sciscione A.** Mechanical methods of cervical ripening and labor induction. *Clin Obstet Gynecol* 2006; 49: 642-57
16. **Schreyer P, Sherman DJ, Arieli S, et al.** Ripening the highly unfavorable cervix with extra amniotic saline instillation or vaginal prostaglandin E2 application. *Obstet Gynecol* 1989; 73:938
17. **Al-Taani MI.** Comparison of prostaglandin E2 tablets or Foley Catheter for induction of labour in Grand Multipara. *Eastern Medical Journal* 2004; 10:547.
18. **Luther E, Gray J, Young D, et al.** Comparison of natural and synthetic prostaglandin E2 in labor induction. *Can Med Assoc J* 1983; 128:1189-1191
19. **Sherman D, Frenkel E, Tovbin J, et al.** Ripening of the unfavorable cervix with extra amniotic catheter balloon. *Obstet Gynecol* 1996; 51:621-627