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

Mandana Mansour Ghanaie; M.D.¹, Mina Jafarabadi; M.D.², Forozan Milani; M.D.¹, Seyed Alaedin Asgary; M.D., Morteza Fallah Kar
dan¹

1 Reproductive Health Research center, Guilan University of Medical Sciences, Rasht, Iran
2 Reproductive Health Research Center, Tehran University of Medical Sciences, Tehran, Iran
3 Department of Urology, Guilan University of Medical Sciences, Rasht, Iran

Received October 2012; Revised and accepted January 2013

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

Correspondence:
Dr. Forozan Milani, Reproductive Health Research center, Alzahra Hospital, Namjo street, Rasht, Iran.
Email: forozanmilani@yahoo.com
means of cervical ripening prior to labor induction: mechanical (the foley catheter balloon and laminarients), and pharmacological (prostaglandins PGE1, PGE2, and PGF2α and estrogen). Mechanical devices dilate the cervix by accessing the fetal membrane, and pharmacological preparations 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 November 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 intracervically (suppository Dinoprostone 5ßphramucia 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. Hyperstimulation 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 intolerant 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 wellbeing test, 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    |
| Oligohydramnios                  | 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).

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 of 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 antepartum 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).

Acknowledgements

We would like to thank all hospital staff who assisted us in this study. The authors declare that they have no conflict of interests.

References

1. Joan Crane St, John’s NF, Line L, Gregory J R. INDUCTION OF LABOUR AT TERM. J Obstet Gynaecol Can 2001;23:717-28.
2. Alec S McEwan. Induction of labour Obstetrics. Gynaecology & Reproductive Medicine2008;18: 1-6.
3. Vellekoop J, Vrouwenraets FP, van der Steeg JW, Mol BW, Roumen FJ. Indications and results of labour induction in nulliparous women: An interview among obstetricians, residents and clinical midwives. Eur J Obstet Gynecol Reprod Biol. 2009;146:156-9.
4. Nicole W. Karjane, Ellen L. Brock, Scott W. Walsh. Induction of Labor Using a Foley Balloon, With and Without Extra-Amniotic Saline Infusion. Obstet Gynecol 2006;107:234–9.
5. Ghanaei M, Sharami H, Asgari A. Labor induction in nulliparous women: a randomized controlled trial of foley catheter with extra-amniotic saline infusion. J Turkish-German Gynecol Assoc 2009; 10: 71-5.
6. Niromanesh S, Mosavi-Jarrahah A, Samkhaniani F. Intracervical Foley catheter balloon vs. pr ostaglandin in preinduction cervical ripening. International Journal of Gynecology and Obstetrics 2003;81: 23–7.
7. D Rouben, F Arias. A randomiaed trial of extra-amniotic saline infusion plus intracervical Foley catheter balloon versus prostaglandin E2 vaginal gel for ripening the cervix and inducing labor in patient with unfavorable cervixes. Obstet Gynecol, 1993; 82:290-4.
8. Vengalil SR, Guinn DA, Olabi NF, Burd LI, Owen J. A randomized trial of misoprostol and extra-amniotic saline infusion for cervical ripening and labor induction. Obstet Gynecol, 1998; 91: 774-9.
9. Barrilleaux PS, Bofill JA, Terrone DA, Magann EF, May WL, Morrison JC. Cervical ripening and induction of labor with misoprostol, dinoprostone gel, and a Foley catheter: A randomized trial of 3 techniques. Am J Obstet Gynecol 2002;186: 1124–9.
10. Culver J, Strauss RA, Brody S, Dorman K, Timlin S, McMahon MJ. A randomized trial comparing vaginal misoprostol versus Foley catheter with concurrent oxytocin for labor induction in nulliparous women. Am J Perinatol 2004;21:139–46.
11. Guinn DA, Goepfert AR, Christine M, Owen J, Hauth JC. Extra-amniotic saline, laminaria, or prostaglandin E(2) gel for labor induction with unfavorable cervix: a randomized controlled trial. Obstet Gynecol 2000;96:106–12.
12. Mullin PM, House M, Paul RH, Wing DA. A comparison of vaginally administered misoprostol with extra-amniotic saline solution infusion for cervical ripening and labor induction. Am J Obstet Gynecol 2002;187:847–52.

13. Charanchakul B, Herabutya Y. Randomized comparison of glycercyl trinitrate and prostaglandin E2 for cervical ripening at term. Obstet Gynecol 2000;96:549-53.

14. Herabutya YO, Prasertsuwat P, Pokpirom J. A comparison of intravaginal misoprostol and intracervical prostaglandin E2 gel for ripening of unfavourable cervix and labor induction. J Obstet Gynecol Res 1997; 23: 369-74.

15. Bugalho A, Bique C, Machungo F, Faundes A. Low-dose vaginal misoprostol for induction of labor with a live fetus. Int J Gynaecol Obstet 1995; 49: 149-55.

16. Wing DA, Rahall A, Jones MM, Goodwin TM, Paul RH. Misoprostol: an effective agent for cervical ripening and labor induction. Am J Obstet Gynecol 1995; 172: 1811-6.

17. Rayburn WF. Preinduction cervical ripening: basis and methods of current practice. Obstet Gynecol Surv 2002; 57: 683-692.

18. Zafarghandi A.Sh., Zafarghandi N., Baghaii N. Foley catheter cervical ripening with extraamniotic infusion of saline or corticosteroids: a double-blind, randomized controlled study. Acta Medica Iranica2004; 4: 338-42.

19. St Onge RD, Connors GT. Preinduction cervical ripening: a comparison of intracervical prostaglandin E gel versus the Foley catheter. Am J Obstet Gynecol 1995;172:687–90.

20. Sciscione AC, McCullough H, Manley JS, Shlossman PA, Pollock M, Colomorgen GH. A prospective randomized comparison of Foley catheter insertion versus intracervical prostaglandin E2 gel for preinduction cervical ripening. Am J Obstet Gynecol 1999;180:55–60.

21. Orhue AA. Induction of labour at term in primigravidae with low Bishop's score: a comparison of three methods. Eur J Obstet Gynecol Reprod Biol 1995;58:119–25.

22. Buccellato CA, Stika CS, Frederiksen MC. A randomized trial of misoprostol versus extra amniotic sodium chloride infusion with oxytocin for induction of labor. Am J Obstet Gynecol 2000; 182: 1039-44.

23. Thomas IL, Chenoweth JN, Tronc GN, Johnson IR. Preparation for induction of labor of the unfavorable cervix with Foley catheter compared with vaginal prostaglandin. Aust NZ J Obstet Gynecol 1986;26:30–5.

24. Perry KG, Larmon JE, May WL, Robinette LG, Martin RW. Cervical ripening: a randomized comparison between intravaginal misoprostol and an intracervical balloon catheter combined with intravaginal dinoprostone. Am J Obstet Gynecol 1998;178: 1333-40.

25. Atad J, Bornstien J, Calderon I, Petrikovsky BM, SorokinY, Aboronovici H. Non pharmaceutical ripening of the labor by a novel double balloon device. Obstet Gynecol 1991;77:146 –51.

26. Bartha JL, Comino-Delgado R, Garcia-Benach F, and et al. Oral misoprostol and intracervical dinoprostone for cervical ripening and labor induction: A randomized comparison. Obstet Gynecol 2000;96:465-9.

27. Bortolus R. Determination of response to intracervical prostaglandin for cervical ripening. Eur J obstet Gynecol Reprod Biol 1999;87:137-41.

28. Ramsey PS, Ramin KD, Ramin SM. Labor induction. Current Opinion in Obstetrics and Gynecology 2000; 12: 463-73.

29. Helmin J, Moller B. Extra amniotic saline infusion is promising in preparing the cervix for induction of labor. Acta Obstet Gynecol Scan 1998; 77: 45-9.

30. Guinn DA, Davies JK, Jones RO, Sullivan L, Wolf D. Labor induction in women with an unfavorable Bishop score: randomized controlled trial of intrauterine Foley catheter with concurrent oxytocin infusion versus Foley catheter with extra-amniotic saline infusion with concurrent oxytocin infusion. Am J Obstet Gynecol 2004;191: 225-9.

31. Karjane NW, Brock EL, Walsh SW. Induction of labor using a foley balloon, with and without extra-amniotic saline infusion. Obstet Gynecol 2006; 107: 234-9.

32. Sherman DJ, Frenkel E, Tovbin J, Arieli S, Caspi E, Bukovsky I. Ripening of the unfavorable cervix with extraamniotic catheter balloon: clinical experience and review. Obstet Gynecol Surv 1996; 51: 621-7.