Labor induction in nulliparous women: a randomized controlled trial of foley catheter with extra-amniotic saline infusion

Nullipar kadınlarda doğum indüksiyonu: foley kateter ve ekstra-amniyotik salin infüzyonunun randomize kontrollü bir karşılaştırması

Mandana M. Ghanaei, Hajar Sharami, Alaeddin Asgari

Guilan University of Medical Science, Iran

Abstract

Objective: This study was undertaken to determine whether the addition of extra-amniotic saline infusion improves the efficacy of the Foley catheter in nulliparous woman undergoing cervical ripening and induction of labor with an unfavorable cervix.

Material and Methods: 152 nulliparous women with a Bishop score less than ≤4 with singleton gestation, vertex presentation, intact membranes referred for labor induction were randomly assigned to 2 groups: Foley catheter alone or extra-amniotic saline infusion (EASI). All women received concurrent dilute oxytocin infusion.Changes in the Bishop scores, interval to active phase and to vaginal delivery, cesarean rate, and outcomes of labor were assessed. Data were analyzed using analysis or the student t-test.

Results: 146 women were studied after 6 exclusions, 73 were assigned to Foley alone and 73 to EASI. At randomization the groups were similar in potential confounders including: maternal age, gestational age, and indications for induction. The EASI group had a significant improvement in Bishop score, 6 hours after induction. The mean time to active phase was 337±141 minutes and 462±183 minutes for the EASI and Foley group respectively (P<0.0001). The mean time to vaginal delivery was 541±265 minutes and 890±259 minutes for the EASI and Foley group respectively (P<0.0001). The cesarean rate and indications for cesarean were not significantly different between the two groups. There were also no differences in mean neonatal birth weight, low Apgar scores and complications including chorioamnionitis, hyperstimulation and neonatal morbidity.

Conclusion: Our study showed that preinduction cervical ripening by extra-amniotic saline infusion with concurrent oxytocin resulted in greater changes in Bishop score, shorter time to active phase and vaginal delivery than the Foley catheter alone in nulliparous women without increasing the cesarean rate and maternal or neonatal morbidity.

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Key words: Extra-amniotic saline infusion, Foley catheter, Labor induction

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Özet

Amaç: Bu çalışmanın amacı uygunsuz serviksi olan nullipar kadınlarda doğum indüksiyonu için ekstraamniyotik salin uygulanmasının foleyu katetere bir üstünlüğünün olup olmadığının araştırılmasıdır.

Gereç ve Yöntemler: Bishop skoru 4 ve altı olan, baş gelişli, intakt membranlı 152 tekil gebe 2 gruba randomize edildi: yalnızca Foley kateter veya ekstraamniyotik salin infüzyonu (EASİ). Tüm gebelere eş zamanlı olarak oksitosin ifüzyonu uygulandı. Bishop skorundaki değişimler, aktif faza ve doğuma kadar geçen süreler, sezaryen oranı ve doğumun seyri değerlendirildi. veriler student-t test uygulanarak karşılaştırıldı.

Bulgular: 6 hasta ekarte edildi ve 146 hasta çalışmaya alındı. 73 hastaya Foley kateter, 73 hastaya da EASİ uygulandı. Tüm hastalar anne yaşı, gebelik haftası, doğum indüksiyonu nedeni gibi faktörler açısından benzerdi. EASİ grubunda indüksiyondan 6 saat sonra Bishop skorunda anlamlı düzelme görüldü. Aktif faza giriş süresi EASİ ve Foley gruplarında 337±141 ve 462±183 dk olara bulundu (P<0.0001). Doğuma kadar geçez süre ise sırayla 541±265 ve 890±259 dk isi (P<0.0001). Sezaryen oranları ve endikasyonları açısından gruplar arasında fark görülmedi. Ayrıca gruplar arasında yenidoğan ağırlığı, apgar skoru, koryoamniyonit de dahil diğer yenidoğan komplikasyonları açısından da fark saptanmadı.

Sonuç: Çalışmamız, nullipar kadınlarda oksitosin indüksiyonu ile birlikte ekstra-amniyotik salin uygulanmasının, yalnızca Foley kateter ile karşılaştırıldığında, sezaryen, mortalite ve yenidoğan morbiditesini arttırmadan Bishop skorlarının iyileştirdiğini, aktif faza ve doğuma geçiş sürelerini iyileştirdiğini göstermiştir.

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Anahtar kelimeler: Ekstra-amniyotik salin infüzyonu, Foley Kateter, doğum indüksiyonu

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Introduction

Labor induction is considered as one of the most common obstetric interventions. Maternal and fetal conditions frequently necessitate delivery before the onset of spontaneous labor. The success rate and safety of labor induction depends on the state of the cervix at the time of labor initiation, and women with unfavorable cervices are at an increased risk of prolonged labor and cesarean delivery (1).

In order to reduce induction complications, numerous methods have been developed for cervical ripening prior to labor induction, including prostaglandins (PGE1, PGE2, and PGF2α),

Address for Correspondence / Yazışma Adresi: *Doç. Dr. Mandana M. Ghanaei, Iran- Rasht- guilan university of medical science rasht, Iran*
Phone: 098-9111313242 e.mail: sharami@gums.ac.ir

mechanical dilatators such as laminaria, Foley catheters, extra-amniotic saline infusion (EASI), oxytocin and relaxin (1, 2). However, no single technique has so far proved to be more efficient than the others . Thus the ideal method of labor induction remains elusive. The use of Foley catheter with or without saline infusion has consistently been associated with rapid improvement in Bishop Scores and shorter labor compared with patients receiving prostaglandins or oxytocin (3, 4, 5).

EASI requires additional resources when compared with the Foley alone, including supplies (extension tubing, a stopcock, normal saline) and the nursing time to set up and maintain the infusion, which increases the costs and charges incurred when using EASI compared with the Foley catheter alone. There are a few published studies comparing the Foley catheter with EASI for induction of labor in women with an unfavorable cervix, (6,7). In addition, in these studies the comparison was made based on the time from induction initiation until vaginal delivery, or cesarean rate, while the mechanism of these methods is cervical ripening which is achieved in the active phase of labor. On the other hand, active phase disorders such as protracted disorders due to cephalo-pelvic disproportion can prolong the duration of labor or can increase the rate of cesarean delivery and can influence trials outcomes.

Therefore our objective in performing this randomized controlled trial was to compare the efficacy of two methods, Foley catheter and EASI, based on the mean time required to reach the active phase of labor in nulliparous women.

Materials and Methods

This study was a randomized clinical trial which was carried out for primiparous women admitted for a medically indicated induction of labor at the prenatal clinic in Alzahra Maternity Hospital, which is affiliated with the Guilan University of Medical Science in Rasht, from May 2004 to August 2005 after being approved by the research committee.

All women were evaluated for eligibility for this trial by resident physicians. Pregnant women were eligible for enrollment if they were: primiparous; between 34 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 place the Foley catheter.

Having given their written consent for participation in the study and after undergoing vaginal examination to determine the Bishop score, the patients were divided randomly into two groups by numbered opaque envelopes: Foley catheter group alone (Foley) or extra-amniotic saline infusion (EASI). 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 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 until delivery after spontaneous expulsion of the Foley catheter.

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. 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 both 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.

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 induction. An abnormal FHR pattern was defined as the occurrence of prolonged fetal bradycardia, recurrent, late or variable decelerations.

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.

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 χ^2 and Fisher exact test were used to compare categorical data. Statistical significances were defined as $P<0.05$.

Result

A total of 152 women with gestational ages of 34- 42 weeks were enrolled in this study. Six were excluded because of major deviations from the study protocol, one had rupture of membrane before intervention, two had spontaneous labor, two because of technical problems in placement of Foley catheter, and one had FHR abnormality which required cesarean section. Of the remaining 146 pregnant women, 73 were assigned to the Foley group and 73 to the extra-amniotic saline infusion (EASI) group. The characteristics of the study population are presented in

Table 1. The groups were similar with respect to maternal age, gestational age, indications of induction and the other factors that might influence outcome interest. All patients were primipara.
Indications for induction of labor were; abnormal fetal testing (33.5%), post- term pregnancy (27.4%) preeclampsia (25.4 %), oligohydramnios or IUGR (13.7 %).There were no significant differences in the mean initial Bishop scores and indications of induction between the two groups (Table 2). The most common causes for pregnancy termination in both groups were abnormal fetal testing (31.5% in EASI group and 35.6% in Foley group). 12 labors were complicated by hyper stimulation that was treated by discontinuing the oxytocin. No patient required cesarean for hyper stimulation. All of the women were delivered before 24 hours with a cesarean rate of 26.7%.
The delivery characteristics of patients are shown in Table 2. In both 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 group (P <0.05). Rate of spontaneous rupture of membranes was higher in the EASI group (P <0.01) 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 group (P <0.0001).44 patients required amniotomy in the active phase of labor. The incidence of hyperstimulation, meconium passage and chorioamnionitis were not significantly different in the two groups.
Table 3 illustrates time intervals from induction initiation to vaginal delivery, cesarean, cesarean rate, and cesarean indications in the two groups. There were no significant differences in the cesarean rates and indications of cesarean between the two groups. The most common cause of cesarean in both groups was FHR abnormalities (11cases in EASI group and 7 in Foley group). The cesarean rate due to failure to progress was similar in both groups (EASI 5; and Foley 4 cases). Only one patient in the EASI group and 2 in the Foley group underwent cesarean due to failed induction.
The mean interval (±SD) from the onset of induction to vaginal delivery in EASI group was significantly lower than in the Foley group (p <0.0001) but the interval to cesarean was similar in the two groups. There were no significant differences in unfavorable maternal and neonatal outcomes such as chorioamnionitis; postpartum metritis; number of Apgar scores less than 7 at 1 and 5 minutes; mean neonatal birth weight and admission to NICU between the two groups (Table 4).
Spontaneous rupture of membranes occurred in 59 patients (80.8%) from the EASI group compared to 46 (63%) from the Foley group (P < 0.01) and time to rupture of membranes occurred 3.5 hours earlier in the EASI group compared with the Foley group (p < 0.0001) . Patients with artificial rupture of membranes were delivered vaginally after 251±100 minutes in the EASI group versus 993±215 minutes in the Foley group (P<0.001) (Table 5).
There were 11 cases of chorioamnionitis (5 in EASI group and 6 in Foley groups) and one case from the EASI group had vaginal cervical injuries following forceps delivery and required blood transfusion.

Tablo 1. Characteristics of Patients

Variables	EASI (n=73)	Foley (n=73)	P_Value
Maternal age (y)	22.9±4	23.1±4	N.S
Mean gestational age (W)	39.5±1.3	39.9±1.7	N.S
Indications for induction:			
Abnormal fetal testing	23 (31.5%)	26 (35.6%)	N.S
Post term pregnancy	21 (28.7%)	19 (26%)	N.S
Preeclampsia	20 (27.4%)	17 (23.3%)	N.S
Olgohydramnios	9 (12.4%)	11 (15%1)	N.S

Discussion

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. Shorter induction to the active phase time by using EASI compared to Foley catheter was the new finding of the current study and was not mentioned in the other studies.
There have been several reports, including randomized trials, describing the use of Foley catheters for labor induction. These trials differ in size of catheter, the volume in the balloon, the use of traction on the cervix, the use of extra - amniotic saline infusion, and the concurrent use of oxytocin (4, 5, 8). However, there are few studies comparing the Foley catheter with EASI for cervical ripening (6, 7).
In our study the mean time from induction initiation up to vaginal delivery in the EASI group was shorter than the Foley group,

Table 2. Labor Characteristics

Variables	EASI (n=73)	Foley (n=73)	P_Value
Initial Bishop score	3.1±1.2	3.5±1.7	N.S
Bishop score ≥7,6 hours after induction	32 (42.2%)	21 (29.1%)	P<0.05
Abnormal FHR	22 (30.1%)	18 (24.6%)	N.S
Hyperstimulation	7	5	N.S
Spontaneous rupture of membranes	59 (80.8%)	46 (63%)	P<0.01
Interval to rupture of membranes (min)	302±189	512±299	P<0.0001
Mean time to active phase	337±141	462±183	P<0.0001

which is similar to results of one study by Karjane et al. (7) The finding of an approximately 5 hours shorter induction to vaginal delivery time differs from that of a similar study published by Guinn et al, which found no statistically significant difference in induction to vaginal delivery time (15. 0 versus 16.3 hours in EASI compared with Foley, respectively, p=0.98),and EASI did not improve the efficacy of the Foley catheter for cervical ripening (6). That study enrolled 100 women and one of the limitation s in their study was failure to successfully place the catheter in 13% of women with a closed cervix and in those women, prostaglandin preparations were used for cervical ripening before placement of Foley catheter.
This might influence the trial outcomes. On the other hand, the higher saline infusion rate (40 ml / hour compared with 30 ml / hour) in our study might have an effect on time to delivery. The women with a closed cervix and extreme posterior orientation of the cervix are not optimal candidates for catheter placement. In our study, the patients were excluded if there was failure to successfully place the Foley catheter.
With use of the Foley catheter with or without EASI the overall rate of cesarean in this study was 26.7%, which is higher than many reports in the literature in women undergoing induction with an unfavorable cervices using a variety of methods for labor induction.(9-11) We believe that one of the reasons for this increase could be the characteristics of the assigned population, being all nulliparous patients, and nuliparity is one the most important factors known to increase cesarean rate due to failure to progress (1, 12).
Extra - amniotic saline infusion increases the risk of chorioamnionitis compared with induction of labor with other methods. In this study, the risk of chorioamnionitis was 6.9 % in the EASI group and 8.2% in the Foley group which were similar to the other studies (6, 7). With respect to maternal or neonatal outcomes and Apgar scores, our data agree with published studies and demonstrate no significant differences between the two groups(3-5, 11). Given the small sample size, however our study is under powered to detect a true difference - and large trials are required to fully examine these secondary outcomes.
Time to delivery could be confounded by co interventions such as artificial rupture of membranes (7, 13). Spontaneous rupture of membranes occurred in the EASI group 3.5 hours earlier than in the Foley group (p<0.0001). In spite of this event, time to active phase and time to normal vaginal delivery were shorter in the EASI group compared to the Foley group. This suggests that earlier artificial rupture of membranes did not bias delivery times in favor of the EASI.
The limitations of the current study are as follows; primary vaginal examination and determination of Bishop Scores was done by more than one resident, which may cause information bias. For comparison of secondary outcomes such as maternal and neonatal morbidity and mortality, we need a larger sample size requiring a large multicentric study.

Tablo 3. Delivery Outcomes

Variables	EASI (n=73)	Foley (n=73)	P_Value
Cesarean delivery	21 (28.8%)	18 (24.6%)	N.S
Indications for cesarean:			
FHR abnormalities	11	7	N.S
Failure to progress	5	4	N.S
Meconium passage	4	5	N.S
Failed induction	1	2	N.S
Mean time to vaginal delivery (min)	541±265	890±259	P<0.0001
Mean time to cesarean (min)	761±320	738±314	N.S

Tablo 4. Maternal and neonatal Outcomes

Variables	EASI (n=73)	Foley (n=73)	P_Value
Chorioamnionitis	5	6	N.S
Postpartum metritis	7	5	N.S
1 min Apgar score ≤7	5	6	N.S
5 min Apgar score ≤7	1	1	N.S
Mean neonatal birth weight (g)	3107±561	3215±262	N.S

Conclusion

Although both methods of labor induction compared in this trail were efficacious in women at high risk for cesarean but did not significantly lower the cesarean rate, EASI compared with Foley catheter resulted in significantly shorter labor without increasing cesarean rate and maternal or neonatal morbidity or poor prenatal outcomes such as low Apgar score, chorioamnionitis and postpartum infections.

Table 5. Mean time to active phase and delivery: Spontaneous versus artificial rupture of membranes

Variables	EASI (n=73)	Foley (n=73)	P_Value
Artificial rupture of membranes			
Time to Active Phase (min)	218±120	476±207	0.009
Time to Delivery (min)	251±100	993±215	0.001
Spontaneous rupture of membranes			
Time to Active Phase (min)	357±135	457±178	0.03
Time to Delivery (min)	566±261	830±268	0.001

References

1. Ramsey PS, Ramin KD, Ramin SM: Labor induction. Current Opinion in Obstetrics and Gynecology, 2000; 12(6): 463-73
2. Chanrachakul B, Herabutya Y: Randomized comparison of glyceryl trinitrate and prostaglandin E2 for cervical ripening at term. Obstet Gynecol, 2000; 96: 549-53
3. Vengali SR, Guinn DA, Olabi NF et al: A randomized trial of misoprostol and extra-amniotic saline infusion for cervical ripening and labor induction. Obstet Gynecol, 1998; 91(5 Pt 1): 774-9
4. Sharami SH, Milani F, Zahiri Z, Mansour-Ghanaei F. A randomized trial of prostaglandin E2 gel and extra-amniotic saline infusion with high dose oxytocin for cervical ripening. Med Sci Monit. 2005;11:CR381-6. Epub 2005 Jul 25.
5. 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.
6. 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.
7. 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
8. 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
9. Herabutya YO, Prasertsawat 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
10. Leszczyñska-Gorzelak B, Laskowska M, Oleszczuk J; Comparative analysis of the effectiveness of misoprostol and prostaglandin E2 in the preinduction and induction of labor. Med Sci Monit, 2001; 7: 1023-8
11. Abramovici D, Goldwasser S, Mabie BC et al: A randomized comparison of oral misoprostol versus Foley catheter and oxytocin for induction of labor at term. Am J Obstet Gynecol, 1999; 181: 1108-12
12. 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
13. Boulvain M, Kelly A, Lobse C, Stan C, Irion O. Mechanical methods for induction of labour. Cochrane Database Syst Rev 2001; 4:CD001233.