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# Comparison between extra amniotic saline infusion vs PGE2 for cervical ripening – a randomised trial

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## Abstract

**Background:** Induction of labour is one of the most important interventions done in obstetric practice. To compare between extra amniotic saline infusion and PGE2 for cervical ripening. Extra amniotic saline infusion achieved a greater number of favourable Bishop score and lead to shorter induction delivery interval and less painful, less chance failure of induction with good perinatal outcome. Hence EASI is one of the effective, safe and economical method of induction of labour.

**Objective**: To compare the induction delivery interval between the two groups, the mode of delivery in two groups and to compare the APGAR score in both the groups

**Materials and Methods**: A prospective study of all case of pregnant women who got admitted to labour ward requiring induction of labour were randomly assigned to EASI or PGE2 between October 2010 to April 2012.

The study was done in 80 women counseling was done regarding both the methods of induction and the choice was given them. 40 women were assigned to extra amniotic saline infusion and 40 women assigned to PGE2 were randomly recruited.

**Results**: results were comparable in terms of maternal age, indication for induction in majority of cases, pre induction bishop score, mode of delivery, intrapartum complications and side effects, neonatal complications, pain scoring by VAS and APGAR score.

The mean post induction Bishop score was higher in extra amniotic saline infusion group by an average of 10. The induction delivery interval was prolonged by an average of 3 hrs in PGE2 gel group. EASI was less painful compared to PGE2.

**Conclusion**: For pre induction cervical ripening the extra amniotic saline infusion is valid alternative for the application of intracervical PGE2 gel. The induction delivery was prolonged (an average of 3 hrs) in PGE2 gel group.

**Keywords**: Extra amniotic saline infusion(EASI), PGE2 gel, Induction of labour, Induction-delivery interval, Bishop score, Cervical ripening.

## Introduction

Induction of labour is one of the most important interventions done in obstetric practice. Induction implies stimulation of contractions before the spontaneous onset of labour, with or without ruptured membranes.(1) After 28 weeks of gestational age using mechanical or pharmacologic methods in order to generate progressive cervical dilation and subsequent delivery.(2) Iatrogenic stimulation of uterine contractions before the spontaneous labour to accomplish vaginal delivery.(3)

Human uterine cervix is a complex heterogenous organ that undergoes intensive changes throughout gestation and parturition.(4) The collagen is degraded by collagenase whose production is under the influence of PGs(5) both intacellularly and extracellularly, to slowly weaken the collagen matrix. So called softening or ripening to allow delivery. As the pregnancy advances close to term, the concentration of collagen decreases with increase in collagenases and elastases activity(6) apparently from a relative dilution of the collagen as is dispersed and remodelled into fine fibers.

- Prostaglandins act synergistically with interleukin-8 to stimulate the fibroblasts to produce hyaluronic acid, which in turn alters the composition and structure of the cervix also have an effect on the uterine muscle, inducing contractions. It has its own limitation like hyperstimulation.
- The extra amniotic saline infusion with a foley's catheter shown to be safe can be well tolerated by the women and should be considered in areas of limited resources.
- The combination of myometrial stretching and direct cervical pressure by the balloon with stimulation of chorioamnion and decidua by saline infusion, maybe synergistic to promote local prostaglandin production and cervical ripening.(7)
- Mechanical separation of membranes from cervix and Lower uterine segment stimulates local cytokines and PG release. These act upon the ground substance of cervix to break down the ground cross-linkages between glycosaminoglycans.

## Aim of study

To compare between extra amniotic saline infusion and PGE2 for cervical ripening.

## Objectives of the study

- To compare the induction delivery interval between the two groups.
- To compare the mode of delivery in two groups.

- To compare the APGAR score in both the groups.

**Inclusion criteria**

1. Eligible women who had obstetric or medical or fetal indications for induction of labour.
2. Singleton gestation
3. Intact membranes
4. Bishop score <6
5. Vertex presentation
6. Gestational age > 28 weeks
7. NST- reactive
8. USG- normal BPP

**Exclusion criteria**

1. Non vertex presentation
2. Uterine contractions(3 contractions lasting for 30 sec/10 min)
3. Ruptured membranes
4. Cephalopelvic disproportion, contracted pelvis.
5. Polyhydramnios ,multiple pregnancy
6. EFW:4000g (big baby)
7. Unexplained vaginal bleeding
8. Placental abruption, placenta previa
9. Prior LSCS/scarred uterus
10. Non reassuring fetal status
11. Clinically detected vaginal infections- genital herpes
12. Inability to obtain the informed consent
13. Latex allergy

## Materials and Methods

A prospective study of all case of pregnant women who got admitted to labour ward requiring induction of labour were randomly assigned to EASI or PGE2 between October 2010 to April 2012.

The study was done in 80 women counseling was done regarding both the methods of induction and the choice was given them. 40 women were assigned to extra amniotic saline infusion and 40 women assigned to PGE2 were randomly recruited.

- Patients selected as per the inclusion criteria and exclusion criteria.
- After obtaining informed consent. A detailed history, complete physical examination, Bishop score assessment. Routine investigations was done for all patients.
- All women will undergo a speculum examination. Cervix was prepared with betadine solution. Prophylactic antibiotic were given to all patients. Women assigned to extra amniotic saline infusion were inserted 18-20 F foley catheter in primigravida and 20-22 F in multigravida beyond the internal OS under direct visualization. Balloon was inflated with 30 ml distilled water, outlet of the catheter connected to a 500ml normal saline bottle through a drip set and the drip rate was adjusted at a rate of ½ ml (8 drops) / min. The catheter was placed in traction by taping it to the medial aspect of the thigh.
- Monitoring pulse ½ hrly, BP 4$^{th}$ hrly, uterine contractions ½ hrly, FHS half hrly, bleeding P/V, drip rate. Cervix has to be assessed for bishop score after 6 hrs or when catheter is expelled. If bishop score remained <6 the infusion was continued for 6 more hours/ until the catheter is expelled, which ever occurred first. Maximum of 12 hrs of induction is done. Oxytocin induction or augmentation was done as per labour induction protocol.
- Subjects assigned to dinoprostone warmed to room temperature(59-86F) just before administration was injected into endocervical canal under direct visualization, subjects remain in left lateral position for 30 min after administration. Monitoring pulse ½ hrly, BP 4$^{th}$ hrly, uterine contractions ½ hrly, FHS Half hrly, bleeding P/V.
- After 6 hours repeat vaginal examination is done and BISHOP score reassigned, if no improvement in Bishop score second dose of PGE2 gel application is done and monitoring of maternal vitals shall be done as already mentioned, if Bishop score was found favourable oxytocin induction / augmentation was done as per protocol of labour ward.

## Results

**Table 1: Comparison of maternal age distribution in the study groups**

| Age in years | EASI group | | PGE2 group | |
|---|---|---|---|---|
| | No | % | No | % |
| 18-20 | 11 | 27.5 | 7 | 17.5 |
| 21-25 | 18 | 45 | 24 | 60.0 |
| 26-30 | 9 | 22.5 | 7 | 17.5 |
| 31-35 | 2 | 5 | 2 | 5 |
| Total | 40 | 100.0 | 40 | 100.0 |
| Mean±SD | 23.28±3.76 | | 23.70±3.59 | |

The mean maternal age in EASI group was 23.28±3.76 and in PGE2 group was 23.7±3.59 (p=0.607) statistically not significant.

**Table 2: Comparison of parity distribution in the study groups**

| Parity | EASI group | | PGE2 group | |
|---|---|---|---|---|
| | No | % | No | % |
| Primi | 23 | 57.5 | 22 | 55 |
| Multi | 17 | 42.5 | 18 | 45.0 |
| Total | 30 | 100.0 | 30 | 100.0 |

p value is 0.822. Primigravida constitutes 57.5% and 55% in PGE2 group. Multigravida constitutes 42.5% and 45% in EASI and PGE2 group respectively. The p value statistically not significant.

**Table 3: Comparison of gestational age distribution in the study group**

| Gestational age(weeks) | EASI group | | PGE2 group | |
|---|---|---|---|---|
| | No | % | No | % |
| 28-37 | 11 | 27.5 | 15 | 37.5 |
| >37 | 29 | 72.5 | 25 | 62.5 |
| Total | 40 | 100 | 40 | 100 |

p value=0.9. The mean gestational age in EASI group was 37.6±3.86. The mean gestational age in PGE2 group was37.5±3.54. The p value statistically not significant.

**Table 4: Comparison of bishop's score in 2 groups**

| Pre Bishop score | EASI group | | PGE2 group | |
|---|---|---|---|---|
| | No | % | No | % |
| 2 | 18 | 45 | 10 | 25 |
| 3 | 13 | 32.5 | 14 | 35 |
| 4 | 7 | 17.5 | 13 | 32.5 |
| 5 | 2 | 5 | 3 | 7.5 |
| Total | 40 | 100 | 40 | 100 |

Majority of women in both the groups had pre induction Bishop score of 2 and 3. In EASI group 18 cases (45%) and 13cases (32.5%) had pre induction Bishop's score of 2 and 3 respectively. In PGE2 group 14 cases (35%) and 13 cases (32.5%) had pre induction Bishop's score of 3 and 4 respectively.

**Table 5: comparison of mean Bishop score in the study groups.**

| Bishop's score | EASI group | PGE2 group | p value |
|---|---|---|---|
| Baseline | 3±0.89 | 3.2±0.93 | 0.32 |
| After 6hours | 10.05±1.56 | 6.37±2.72 | <0.001 |
| p value | <0.001 | <0.001 | |

p value was statistically significant. The mean post induction Bishop score of the study group was 10.05±1.56 in EASI group and 6.37±2.72in PGE2.

**Table 6: Mode of delivery during the study groups:**

| Normal delivery | | | | LSCS | | | |
|---|---|---|---|---|---|---|---|
| EASI | % | PGE2 | % | EASI | % | PGE2 | % |
| 32 | 80% | 29 | 72.5 | 8 | 20 | 11 | 27.5 |

EASI had 80% of vaginal delivery and PGE2 had 72.5%. LSCS was 20% in EASI and 27.5% in PGE2.

**Table 7: Indication for LSCS.**

| LSCS indication | EASI group (n=40) | | PgE2 group (n=40) | |
|---|---|---|---|---|
| | No | % | No | % |
| Failed induction | 0 | 0.0 | 3 | 7.5 |
| Failure to progress | 3 | 7.5 | 2 | 5.0 |
| Fetal distress | 3 | 7.5 | 5 | 12.5 |
| Hyper stimulation | 0 | 0.0 | 1 | 2.5 |
| Patient not cooperative | 1 | 2.5 | 0 | 0.0 |
| Arrest of decent | 1 | 2.5 | 0 | 0.0 |

8 cases (20%) in EASI and 11 cases (27.5%) in PGE2 had LSCS for various indications. Indications for LSCS in EASI group was failure to progress, fetal distress. Where as in PGE2 group it was failed induction, fetal distress and failure to progress.

**Table 8: Comparison of complications distribution**

| Complications | EASI group (n=40) | | PgE2 group (n=40) | |
|---|---|---|---|---|
| | No. | % | No. | % |
| No | 36 | 90 | 38 | 92.0 |
| Yes | 4 | 10 | 3 | 7.5 |
| FSB | 2 | 5 | 1 | 2.5 |
| Deeply asphyxiated | 2 | 5 | 2 | 5.0 |

There were 2 cases (5%) of fresh stillborn in EASI group. Babies who became stillborn were, one had congenital anomaly incompatible with life and the other one was a case of nonimmune hydrops fetalis. There were 2 cases(5%) of deeply asphyxiated baby in EASI due to severe IUGR.

There were 2 cases (5%) of deeply asphyxiated baby in PGE2 due to oligohydramnios and one case of FSB due to severe pre-eclampsia at an early gestation.

**Table 9: Visual analogue scale (VAS) distribution in both the groups**

| VAS | EASI | PGE2 |
|---|---|---|
| | 4.5+/-0.59 | 8.57+/-0.5 |

p =0.000 which is statistically significant.

**Table 10: Comparison of APGAR score distribution**

| APGAR score at | EASI | PGE2 | p value |
|---|---|---|---|
| 1 min | 6.775±2.47 | 6.78±1.98 | 0.99 |
| 5 min | 7.9±2.75 | 7.93±2.04 | 0.95 |

The mean APGAR score at 1 min in EASI group was 6.775±2.47 and in PGE2 gel group was 6.78±1.98. The p value was 0.99 statistically not significant.

The mean APGAR score at 5 min in EASI group was 7.9±2.75 and in PGE2 gel group was 7.93±2.04. The p value was 0.95 statistically not significant.

## Discussion

In our study, mean maternal age were comparable with studies of Guinn et al[10] and Goldman et al.

The number of primigravidas in this study group were 23(57.5%) in EASI group and 22 (55%) in PGE2 group. The number of multigravida in this study group

were 17(42.5%) in EASI group and 18(45%) in PGE2 group. In our present study percentage of primigravidaand multigravida between two groups were comparable with study of Schreyer et al.[7]

The mean gestational age in EASI group was 37.6±3.86. The mean gestationl age in PGE2 group was 37.5±3.54. in our study mean gestational age between groups were comparable with studies of Goldman et al and Sherman et al.[11]

Rouben and Arias also compared EASI with intravaginal prostaglandins and showed that women who received EASI achieved a Bishop score of 6 or more and 5 or more with intravaginal prostaglandin, similar to our findings of 10 or more in EASI and 6 or more in PGE2 gel.[9]

With respect to the mode of delivery PGE2 had increased rate of cesarean section compared to EASI and correlates well with the study by Rouben et al showed 46% of cesarean section rate in PGE2 group.[9]

The majority of women in both the groups 32 cases (80%) in EASI group and 29 cases(72.5%) in PGE2 group had spontaneous vaginal delivery. 8 cases (20%) in EASI and 11 cases (27.5%) in PGE2 had LSCS for various indication.

Goldman et al study showed decrease in APGAR score at 1 min and 5 min in both groups, but higher percentage in PGE2.

Our study demonstrates that extra amniotic saline infusion results in more women achieving favourable Bishop score than dinoprostone gel.

With respect to the other studies some comparisons can be drawn. Schreyer et al[8] found that 67% receiving EASI achieved a significant change in the Bishop score compared with 39% who achieved a change of 3 points after intravaginal prostaglandin

## Conclusion

Vaginal delivery is considered to be the success of obstetrics. Many pregnant women requiring induction of labour come with unfavourable cervix. Achieving vaginal delivery through pre induction cervical ripening is an obstetric challenge.

There are various methods which have their own merits and demerits. The most commonly used PGE2 has got its own disadvantages. There is a hope raised by mechanical methods of induction and one of them is EASI.

EASI is one such mechanical method which was compared with commonly used PGE2. EASI is as effective as PGE2 in achieving vaginal delivery. It has got other advantages like shorter induction delivery interval, less painful, less chance failure of induction with good perinatal outcome.[12] Hence EASI is one of the effective, safe and economical method of induction of labour.

## Disclosure of interests

None declared. Completed disclosure of interests form available to view online as supporting information.

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