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Extra Amniotic Saline Infusion in Cervical Ripening and Induction of Labour and Its Effect on Foeto Maternal Out Come

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ABSTRACT

Background: *There are various pharmacological and non-pharmacological methods available for ripening and induction of Labour. These methods can produce potential harm to the mother and fetus. Induction of labour can produce risk of uterine hyper stimulation and rupture and foetal distress.*

Aim

The aim of this study is to

1. *Evaluate the effectiveness and safety of foley's catheter with Extra Amniotic Saline Infusion in cervical ripening and induction of labour.*
2. *To assess the Induction delivery interval, mode of delivery and foetomatenal outcome.*
3. *To assess the Intrapartum and post-partum complications.*

Materials and Methods: *This is a prospective observational study conducted in the Department of Obstetrics and Gynecology, Government Medical College, Kottayam from January 2012 to October 2012. 201 Antenatal women were included in this study.*

Result: *The mean pre treatment Bishop Score were 2.125 ± 0.609, 75.6% were having Bishop's Score of 2. There was significant improvement in Bishop's Score after EASI. Maximum patients (76.6%) achieved vaginal delivery. Incidence of caesarean section was very much reduced (18.4%). The mean Induction Delivery interval was 11.02 hours. The mean Apgar score at 5' was 8.94. 99 % Babies having Apgar score > 7 at 5 minute. No significant foeto maternal complications compared to other inducing agents were observed in the current study. These patients were followed up in the post-partum period and no significant post-partum complications were observed.*

Conclusion: *EASI is a simple, inexpensive easily available method of induction with shorter induction delivery interval, increased vaginal delivery rate with not much significant maternal, foetal or neonatal complications. No serious maternal complications in the post-partum period and no significant morbidity and mortality to the baby in the neonatal period.*

Keywords: *EASI, Foley's catheter, Induction*

BACKGROUND

Induction of labor refers to the process by which uterine contractions are initiated by medical or surgical means before the onset of spontaneous labor. The main aim of induction of labor is to achieve maximum number of vaginal births without producing much harm to the mother and fetus. An ideal ripening agent should be inexpensive, easily

available, simple to use, easily reversible, effective and safe for the mother and fetus.

Other pharmacological agents prostaglandin E2 (Dino prostone) and prostaglandin E1 (Misoprostol) are effective and easy to administer, but are not readily reversible, continuous monitoring is needed. Produce various adverse effects including pyrexia, nausea, vomiting, diarrohea and hyperstimulation that lead to uterine tachysystole, uterine rupture and fetal morbidity and mortality.

In multiparous woman and woman with history of previous caesarean section, prostaglandins especially Misoprostol is associated with high risk of uterine rupture. But EASI can be used as a safer method in such patients with good maternal and fetal outcome.

EASI is safe and well tolerated by the woman and can be considered in areas with limited resources. There is relative infrequency of reported major complications. It can be also used safetly in patients with previous caesarean section for cervical ripening and induction of labor.

AIM OF STUDY

This study evaluates the Effectiveness, Safety, Rate of Vaginal Births, Feto Maternal outcome and any Intrapartum and Post-partum complications.

MATERIALS AND METHODS

This is a prospective observational study conducted in the Department of Obstetrics and Gynaecology at Government Medical College, Kottayam during the period from January 2012 to October 2012. Patients were selected after proper counseling and getting their consent. A total of 201 antenatal women with maternal or fetal indication for induction of labor and unfavorable cervix were taken up for this study.

Study Design: Prospective observational study

Study Population: Total 201 antenatal women with maternal and fetal indication for induction of labor and unfavorable cervix were taken up for the study.

Inclusion Criteria

1. Singleton gestation
2. Intact membrane
3. Cephalic presentation
4. Unfavourable cervix
5. Adequate pelvis

Exclusion Criteria

1. Non- Reactive NST
2. Low Lying placenta
3. Abruptio placenta
4. Patients in Labor
5. Glaucoma
6. Uterine Anomalies
7. Malpresentation
8. Contracted pelvis
9. Herpes Simplex Infection

Method: Every woman included in this study was counseled and consent taken. Detailed history taking, clinical examination and obstetric examination done to satisfy the inclusion and exclusion criteria. Vaginal examination was done to assess the pelvis and Bishop's Score of cervix. Cardio Tocogram (CTG) evaluation was done and only those with reactive and reassuring CTG were included.

Procedure

1. Equipment
2. Self retaining cusco's speculum
3. 18-gauge Foley catheter with 30ml size balloon
4. Sponge holding forceps
5. Isotonic saline – at room temperature
6. Syringe 10ml / 20ml
7. Adhesive tape

Informed consent taken. Broad spectrum antibiotics started half an hour before the procedure. Patient is placed in the lithotomy position. Vulvo vaginal area cleansed with antiseptic solution. Cusco's speculum is inserted into the vagina and cervix visualized. Using the sponge holding forceps, the Foley's catheter is passed through the cervical canal past the internal OS. The balloon inflated with 30-40 ml saline. The speculum removed and the catheter gently withdrawn until it rests at the level of the internal OS. With moderate traction on the catheter, 200 ml isotonic saline is infused through the

catheter into the extra amniotic space. With the same traction, the catheter is taped into the inner aspect if thigh, the catheter is blocked by putting a knot on the catheter before taping it. Catheter is left in place for 24 hrs.

Fetal heart is checked after completion of the procedure. Patient is observed for uterine activity, pulse rate, blood pressure, respiratory rate and fetal heart rate. Catheter is removed after 24 hrs, per vaginal examination is done when the catheter fells out or after removal at 24 hrs to assess the Bishop's Score. When the cervix has become favourable [ie,Bishop Score > = 6] induction [ARM, Pitocin or ARM + Pitocin] started. If cervix is unfavourable<6 other ripening methods are used. The pediatrician in charge attended each delivery to assess the Apgar score. The following data were collected from each case-Timing of EASI insertion, Timing of EASI Expulsion/ Removal, Induction Method needed, Need for Oxytocin augmentation, Mode of delivery-Vaginal, Vacuum, Forceps, Need for Caesarean Section (CS) and its indication. EASI delivery interval and induction delivery interval, Apgar score of baby at 1 minute and 5 minutes, SCNU admission, Feto Maternal complications. Any side effect of the drugs. Any post-partum complications for the mother.

STATISTICAL ANALYSIS

Data collected

SPSS version 17 was used to analyse the data. Student's t-test used to find out the association of quantitative variables and chi-square test for qualitative variables. P value less than 0.05 was taken as statistically significant.

OBSERVATIONS

Table I: Parity Distribution-VS Post treatment Bishop's Score

Gravida	Frequency	%	BS ≥ 6	%	≤ 6	%
Primi	168	83.6%	125	74.4%	43	25.6%
Multi	33	16.4%	31	93.9%	1.2	6%
Total	201	100%				

Out of 201 patients 168 (83.6%) were primigravida and 33 (16.4%) were multigravida, 74.4% of primi achieved Bishops Score ≥ 6, 93.3% of multi achieved Bishop's Score ≥ 6

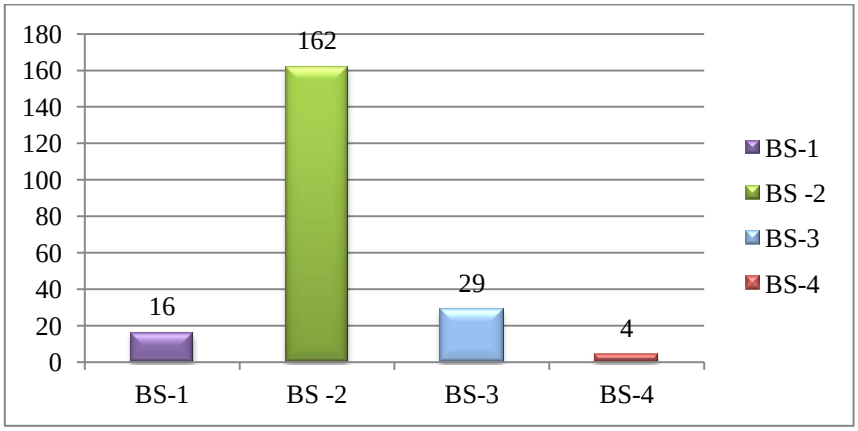

Figure I: Pretreatment Bishops score

All cases had unfavourable cervical score from 1-4, Bishop's Score of 1-2 observed in 83.5% cases, Bishop's Score of 3-4 observed in 16.5 % cases. Mean Bishop's score 2.12 ± 0.60

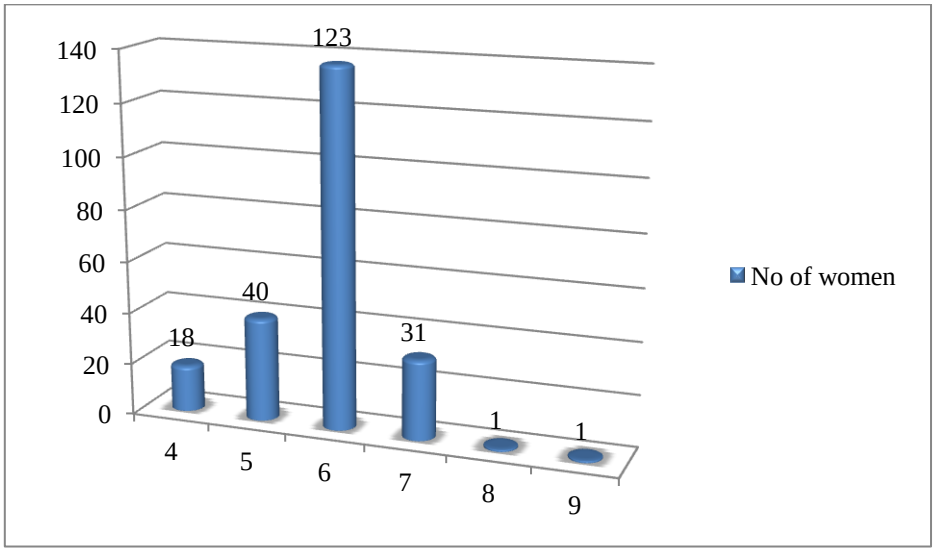

Figure II: – post treatment Bishops score

Maximum patients - 123 (61.2%) achieved Bishops score 6
31 (15.4%) Score 7
1patient each score 8and9

Total 156-77.6% achieved favourable Bishop's Score ≥ 6
Mean post treatment Bishops Score 5.86 ± 0.86

Table II: Parity and Improvement in Bishop's Score

Gravida		N	Mean	Standard Deviation	t	P: value	Significance
Pretreatment	Primi	168	2.13	0.62	0.35	0.73	P:>0.5
	Multi	33	2.09	0.58			
Post treatment	Primi	168	5.79	0.88	2.81	0.01	P:<0.5
	Multi	33	6.24	0.66			

No significant difference in the pretreatment Bishop's Score between primi and multi. Multi achieved more post treatment Bishop's score than primi.

Table III: Mode of Delivery and Correlation with Post Treatment Bishop's Score

Post Treatment Bishop's Score	Mode of Delivery			Total
	Normal	Instrumental	CS	
Score < 6	27 (60%)	3 (6.7%)	15 (33.3%)	45
Score > 6	127 (81.4%)	7 (4.48%)	22 (14.1%)	156
Total	154	10	37	201

Chi square = 9.4 P = .009

Out of 156 patients with favourable Bishop's Score, 127 (81.4%) delivered normally 22-undergone LSCS (14.1%). 7 (4.48%) instrumental delivery.

Out of 45 patients who failed to achieve favourable Bishop's score required PGE1, for ripening and 27(60%) delivered normally, 15(33.3%) require LSCS and 3(6.7%) instrumental delivery. The observed differences are statistically significant.

Table: IV Mode of Delivery

Mode	Frequency	Percentage
Vaginal	154	76.6%
Instrumental	10	5.96%
CS	37	18.4%
Total	201	100%

154 patients (76.6%) delivered vaginally - so maximum vaginal delivery
10 patients (5%) - Instrumental Delivery
37 patients (18.4%) - LSCS
Out of 154 patients, 53 patients (34.49%) delivered by 24hours from the starting of ripening and 101 patients (65.51%) delivered by 24-48 hours.

Mean EASI delivery interval 26.92 hrs. Mean Induction delivery interval 11.10 ±6.02hrs

Table V: Induction Delivery Interval Based on Parity

IDI	Gravida	N	Mean	Standard Deviation	t	P Value
	Primi Multi	167 33	11.77 7.71	6.22 3.23	3.64	0.00

Significant difference in the mean score of primi and multi regarding IDI [P Value < 0.05] – means multipara have shorter induction delivery interval.

Table VI: Indication for Caesarean Section

Indication	Frequency	BS > 6	BS < 6
NRFHR	15 (7.5%)	10	5
Failed Induction	12 (6)	3	9
Thick MSAF	4 (2)	4	0
Protracted Active phase	3 (1.5)	3	0
Cord Prolapse	1 (5%)	1	0
Failed Trial	1 (5%)	1	0
Abruption gr II	1 (5%)	0	1
Total	37	22	15

Main indication for CS was NRFHR 7.5 % followed by failed induction 6%

Out of 15 cases of NRFHR, 10 cases augmented with oxytocin. 9 cases out of 12 cases of failed induction, PGE1 was used as a second ripening method.

Table VII: Neonatal Outcome

New Born Apgar Score	Mean	N	Standard Deviation	t	p Value
5 minute	8.94	201	0.39	1.33	0.18
1 minute	8.35	201	1.07		

Mean Apgar Score at 1 minute and 5 minute did not differ significantly [P Value > 0.05]

Maternal Complications

No cases of fertile illness, chorioamnionitis, vaginal bleeding. No reported postpartum sepsis.

Fetal complications

Few cases of NRFHR most probably because of other augmenting agents like oxytocin. One case of cord prolapse. No significant maternal or fetal complications observed in this study.

Table VIII: SCNU Admission Vs Mode of Delivery

Mode of Delivery	Fetal Complications		Total
	No Admission	Admission	
Normal	139	15	154 (9.74%)
Instrumental	10	0	10 (0%)
CS	27	10	37 (27%)
Total	176	25	201

DISCUSSION

This study included primi (83.6%) and multi (16.4%). Gestational age ranged from 32 weeks 6 days to 40 weeks 4 days with 77.6% term and 22.4% preterm cases. All cases had unripe cervix <4 Bishop's score.

The mean pretreatment Bishop's score was 2.125 ± 0.609.

156 patients achieved a post treatment Bishop's score of 6 before 12 hours. 40 patients achieved Bishop's score of 6 between 12 hours and 24 hours. 52 patients achieved BS 6 at 24 hours[1].

Compared with prostaglandins, more number of patients achieved better post treatment Bishop's score with EASI use[2] not much significant difference in the pretreatment BS for primi and multi. But significant difference in the post treatment BS in primi and multigravida with higher mean post treatment Bishop's score (P < 0.05).

Result of present study showed that maximum vaginal delivery occurred with EASI compared to other inducing agents. In a comparative study with misoprostol and dinoprostone group- more number of vaginal delivery is with Foley's catheter group[3]. Compared to EASI and Dinoprostone gel more favourable Bishop's score with EASI[4]. The overall caesarean delivery rate was only 18.4% which is less than that observed in various other studies[5].

Incidence of CS in patients who achieved favourable BS is 14.1% compared with those who required PGE1, for ripening the cervix. The rate of CS was 33.3%. CS rate is higher (28.8%) with EASI than with foley alone (24.6%). The reason may be

due to the characteristic of the group. All are primigravida compared to multigravida[6].

Indications for CS were mainly due to failed induction (5.9%) Fetal distress (7.46%)- which may not be directly due to EASI, because all these cases are after spontaneous expulsion of EASI or removal after 24 hours.

No case of hyper stimulation reported in the present study. So NRFHR may be not due to EASI. May be because of the augmenting agents like oxytocin.

CS due to NRFHR was 15 and 10 cases were from oxytocin augmented patients. CS due to failed induction was 12 cases of which 9 cases are from the patients who required PGE1 as a second ripening agent.

Mean induction delivery interval in this study was found to be 11.02 $\pm$6.10 hrs [6]

EASI delivery interval was 26.92 $\pm$ 9.40 hrs. Similar with Goldman et al4(25.9hrs)

Significant induction delivery interval between primi (11.77 hrs) and Muti (7.71 hrs) were found in the present study.

Induction delivery interval in this study was found to be shorter than reported studies[5].

Neonatal outcomes were favourable in this study compared with other inducing agents. No significant fetal/Neonatal complications observed. The mean Apgar Score at 1 mt and 5 mt not differr significantly. Only 3.4% of babies had Apgar Score < 7 at 1 mt and 0.99% (2 babies) had low Apgar Score at 5 mts. (Both these babies were early neonatal death and born by LSCS. More favourable finding than reported studies[6].

In a comparative study of EASI alone with EASI and dexamethasone reported that 5.3% neonates has Apgar <7 at 5 mt and 5.3% SCNU admission[7].

There are 25(12.4%) admission in SCNU in our current study, slightly higher than published studies. In most reported studies the study group included term patients. But in the present study of EASI cases, both preterm (22.4%) and term pregnancies were included. Prematurity may be the cause for SCNU admissions in the present study[8].

Due to lack of large trials, published data on complication of EASI induction are less. Few patients 4 out of 66(6.1%) had chorioamnionitis with EASI[5]. In the present study no case of chorioamnionitis or female morbidity reported. Use of prophylactic antibiotics before induction with EASI can reduce the rate of chorioamnionitis. Maternal adverse events were rare and unrelated to method of inductions.

The main complication reported in studies were acute transient Febrile reaction, chorioamnionitis, NRFHR, vaginal bleeding etc[9]. No such fetomaternal complications observed in the current study.

In the follow up study cervical ripening with Foley's catheter did not increase the risk of preterm birth in the subsequent pregnancy[10]. Mild bleeding shortly after catheter insertion or after rupture of membranes had been observed in the reported studies[2].

In the present study, prophylactic broad spectrum antibiotic given half an hour before the procedure for all patients. Prophylactic antibiotic was given only in cases of Group B, Streptococcus prophylaxis or where there is clinical chorioamnionitisin the published studies.

These patients were followed up in the post-partum period also. No cases of febrile illness, or postpartum endomyometritis observed in the present study.

SUMMARY AND CONCLUSION

EASI is an effective method for cervical ripening. It does not produce painful uterine contractions compared to other inducing agents like prostaglandins which produce severe painful uterine contractions, hyperstimulation and even uterine rupture. It is simple to use and it has potential for reversibility. EASI application resulted in successful induction within maximum number of vaginal deliveries. Induction delivery internal is shortened. Number of operative deliveries are decreased.

Feto maternal outcome is better with EASI than with other inducing agents. Not much Feto maternal complications were observed in the present study. It is well tolerated by women and there were no systemic and serious maternal side effects.

Fetal outcome also is favourable with less number of Fetal and Neonatal morbidity and mortality.

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