THE EFFECTIVENESS AND SAFETY OF FOLEY'S CATHETER WITH EXTRAAMNIOTIC SALINE INFUSION (EASI) ON CERVICAL RIPENING AND INDUCTION OF LABOUR

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ABSTRACT

BACKGROUND

The favourability of cervix is of fundamental importance for successful induction of labour. Unfavourable cervix should be ripened before induction is started. The various methods available for cervical ripening include both pharmacological and non-pharmacological. Pharmacological methods though effective are associated with significant lethal untoward effect on mother, foetus or newborn and expensive also.

The aim of this study is to evaluate the effectiveness and safety of Foley's catheter with extra amniotic saline infusion (EASI) on cervical ripening and induction of labour.

MATERIALS AND METHODS

This prospective observational study was conducted in the Department of Obstetrics and Gynaecology, Government Medical College, Kottayam, from January 2012 to October 2012. Total of 201 antenatal women who satisfied the inclusion and exclusion criteria were included in this study. The main outcome variables were the number of subjects with favourable Bishop's score, mode of delivery, induction delivery interval, newborn Apgar score and incidence of intra-amniotic infection or postpartum endomyometritis.

RESULTS

The mean pretreatment Bishop's score was 2.125±0.609, 75.6% were having Bishop's score 2. There was significant improvement in Bishop's score after EASI. 156 patients achieved Bishop's score >6 after EASI. Maximum patients (76.6%) achieved vaginal delivery. The caesarean rate was 18.4%. The mean induction delivery interval was 11.02 hours. 68.2% women required oxytocin induction or augmentation. The mean Apgar score at 5 minutes was 8.94 with 99% babies having Apgar score >7 at 5 minutes and 12.34% NICU admissions. No maternal complications were observed.

CONCLUSION

EASI is an effective method for cervical ripening and EASI ripening resulted in successful induction with shorter induction delivery interval, low caesarean section rate with no maternal, foetal or neonatal complication. EASI is simple, reversible, inexpensive, easily available and no refrigeration is needed. With the use of prophylactic antibiotics, the safety can be increased.

KEYWORDS

EASI, Bishop's Score, Foley's Catheter, Ripening, Induction, Oxytocin.

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BACKGROUND

Induction of labour refers to the process whereby uterine contractions are initiated by medical or surgical means before the onset of spontaneous labour. The aim of induction of labour is to achieve vaginal birth before the onset of spontaneous labour and it is a clinical intervention that has the potential to confer major benefits to the mother and newborn. The state of cervix is one of the important predictor of successful labour induction. If the cervix is unfavourable, a successful vaginal birth is less likely. Cervical ripening is of fundamental importance for successful induction of labour. Cervical ripening or preparedness for induction should be assessed before induction is started. Various scoring system for cervical assessment have been introduced. An ideal ripening method should be inexpensive, easy, effective, reversible, simple to use and safe for the mother and the foetus. The various methods available for cervical ripening of an unfavourable cervix include both pharmacological and non-pharmacological. Studies show that pharmacologic agents,

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prostaglandin E2 (dinoprostone) and prostaglandin E1 (misoprostol) are effective and simple to administer. However, these agents are not readily reversible; require continuous monitoring once administered and are fraught with adverse effects, including fever, nausea, vomiting, diarrhoea and hyperstimulation that may lead to uterine tachysystole, uterine rupture and foetal morbidity and mortality. There are absolute and relative contraindications for the use of prostaglandins. In multiparous woman and woman with history of previous caesarean sections, prostaglandins especially misoprostol is associated with high risk of uterine rupture.

Mechanical dilation methods include transcervical Foley catheter alone and transcervical Foley catheter with Extraamniotic Saline Infusion (EASI) for enhanced endogenous prostaglandin secretion. Transcervical balloon with or without EASI is a well-established means of cervical ripening and dilation. The popularity of the procedure stems from its ease of use, low cost, effectiveness and relative infrequency of reported major complications. This method has been shown to be safe and well tolerated by the women and should be considered in areas with limited resources. Studies shows that balloon catheter can be safely used in patients with previous caesarean section for cervical ripening and labour induction. Different studies conducted so far shows that EASI is as effective as prostaglandins, safe and much cheaper than prostaglandins. EASI is simple to use, materials are easily available and no need of refrigeration. It is easily reversible. Maternal and foetal complications are rare. Considering these factors, EASI should be seriously considered as a method of first choice for cervical ripening especially in resource poor settings.

Aim of Study

The aim of this study is to evaluate the effectiveness and safety of Foley's catheter with EASI on cervical ripening and induction of labour.

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, after getting the approval from the Ethical Committee. Patients were included after proper counseling and after getting their consent.

Study Design

Prospective observational study.

Study Population

A total of 201 antenatal women with maternal or foetal indication for induction of labour and unfavourable cervix were taken up for this study.

Inclusion Criteria

1. Singleton gestation.
2. Intact membrane.
3. Cephalic presentation.
4. Unfavourable cervix (Bishop score <4).
5. Favourable pelvis.

Exclusion Criteria

1. Patients in labour.
2. Non-reactive NST.
3. Low lying placenta.
4. Placental abruption.
5. Cardiopulmonary diseases.
6. Glaucoma.
7. Herpes simplex infection.
8. Uterine anomalies.
9. Malpresentation.
10. Contracted pelvis.

Data Collection Method

Every pregnant woman included in this study was counselled and consent was obtained. All patients were submitted for elaborate clinical examination and obstetric examination along with detailed history taking to satisfy the inclusion and exclusion criteria. Vaginal examination to assess the pelvis and for Bishop's score determination. Obstetric ultrasound examination was done to confirm the gestational age, evaluate the foetal wellbeing and to localise the placenta. Cardiotocogram (CTG) evaluation was done and only those with reactive and reassuring tracing were included.

PROCEDURE

Equipment

1. Self-retaining Cusco's speculum.
2. 18-gauge Foley catheter with 30mL size balloon (30-40 mL).
3. Sponge Forceps.
4. Isotonic saline - at room temperature.
5. Syringe 10 mL/20 mL.
6. Adhesive tape.

Informed consent is taken and broad-spectrum antibiotics started half an hour before procedure. Patient is placed in the lithotomy position. Vulvovaginal area cleansed with antiseptic solution. Cusco's speculum is inserted into the vagina and cervix visualised. 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 internal os. With moderate traction on the catheter, 200mL isotonic saline is infused through the catheter into the extraamniotic space. With the same traction, the catheter is taped on to the inner aspect of thigh. The catheter is blocked by putting a knot on the catheter before taping it. Catheter is left in place for 24 hours. Foetal heart is checked after completion of the procedure. Patient is observed for uterine activity, pulse rate, blood pressure, respiratory rate and foetal heart rate. If catheter has not

fallen out, it is removed after 24 hours. Vaginal examination is done when the catheter falls out or after removal at 24 hours to assess the Bishop score. When the cervix has become favourable (i.e., Bishop score >=6) induction (ARM, Pitocin or ARM + Pitocin) started. If cervix is unfavourable (Bishop score <6) other ripening method is used. The paediatrician 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, Bishop's score before EASI insertion, Bishop's score after EASI expulsion/removal, induction method needed, need for oxytocin augmentation, mode of delivery-spontaneous, vacuum, forceps, need for caesarean section (CS) and its indications, EASI delivery interval and induction delivery interval, Apgar score of baby at 1 minute and 5 minutes, SCNU admissions, detection of maternal and foetal complications and side effects. Mother followed up for postpartum endomyometritis.

Ethics IEC No- 52/2012

Statistical Analysis

The data were collected and tabulated into excel sheet and SPSS version 17 was used to analyse the data. Student's t-test was used to find out the association of quantitative variables and Chi-square test was used for qualitative variables and p value less than 0.05 was taken as statistically significant. Descriptive statistics using percentage analysis was also used.

RESULTS AND OBSERVATIONS

A total of 201 cases, which included all the cases of EASI during the study period from January to October 2012 were analysed.

Age Distribution		
Age Group	**Frequency**	**Percentage**
Upto 20	7	3.5%
21-25	75	37.35
26-30	86	42.8%
31-35	25	12.4%
36-40	7	3.5%
41-45	1	0.5%
Total	**201**	**100.0%**

Table 1. Frequency of Age Distribution

In this study, the maximum number of patients (42.8%) belonged to the age group of 26-30 yrs. followed by 21-25 yrs. (37.3%). Youngest patient was 19 yrs. old and the oldest one was 41 yrs. of age. Mean maternal age is 26.81±40.6 yrs.

GA	Group	Frequency	Percentage
32-34 weeks+6 days	1	4	2.0%
35-36 weeks+6 days	2	41	20.4%
37-40 weeks	3	142	70.6%
40-42 weeks	4	14	7.0%
	Total	**201**	**100%**

Table 2. Gestational Age Frequency

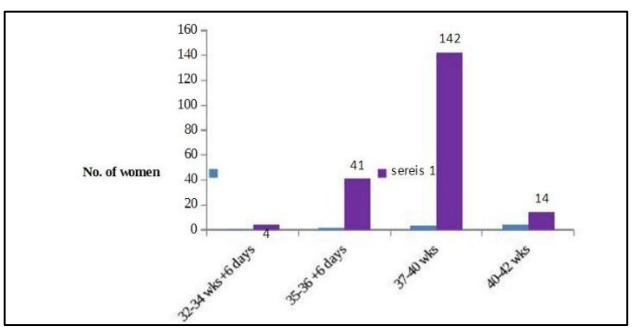

Figure 1. Gestational Age Distribution

The mean gestational age in this study was 269.42±11.01 days. 77.6% term induction and 22.39% preterm inductions since all cases of EASI during the study period were included.

Gravida	Frequency	Percentage	BS ≥6	Percent	BS <6	Percent
Primi	168	83.6%	125	74.4%	43	25.6%
Multi	33	16.4%	31	93.9%	2	6.1%
Total	**201**	**100%**				

Table 3. Parity Distribution - vs. Post Treatment Bishop's Score

Out of the 201 patients who required cervical ripening, 83.6% were primigravida and 33 (16.4%) were multigravida, while 74.4% of primi achieved Bishop's score ≥6, it was 93.9% among multigravida.

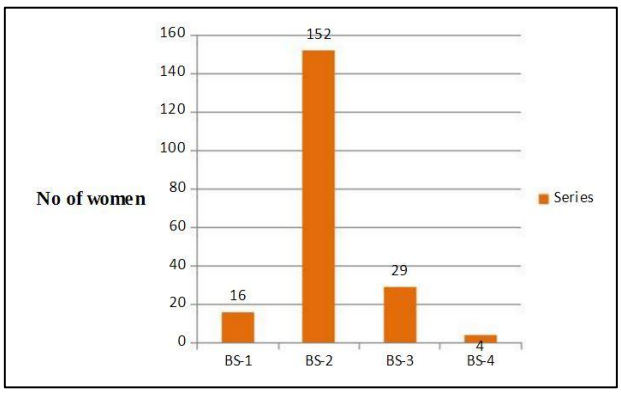

Figure 2. Pretreatment Bishop's Score

On assessment of pre-treatment Bishop scoring, it was observed that all the cases had unfavourable cervical scoring from 1-4. Bishop score of 1-2 was observed in 83.5% cases, whereas 16.5% had Bishop's score of 3-4. The mean Bishop score is 2.12±0.60.

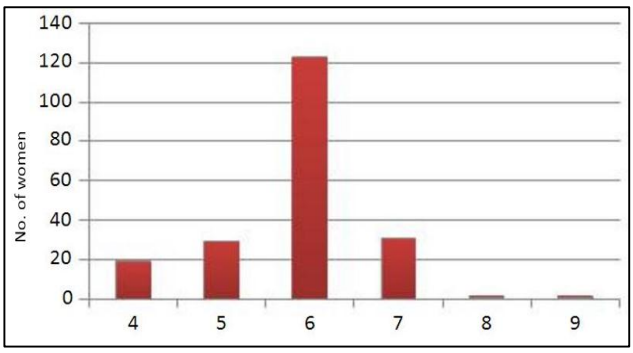

Figure 3. Post Treatment Bishop's Score

Maximum patients (123, 61.2%) attained Bishop's score 6, 31(15.4%) patients score7and 1 patient score 8 and score 9 each. In total, 77.6% (156) patients achieved favourable Bishop's score (>=6). The mean post treatment Bishop's score was 5.86±0.86.

	Mean	N	Std. Deviation	t	P Value	Sig.
Pretreatment	2.12	201	0.61	53.64	0.00	P<0.5
Post treatment	5.86	201	0.867			

Table 4. Improvement in Bishop's Score

There was statistically significant difference in the pre and post treatment Bishop score, which shows that EASI is effective in cervical ripening.

	Gravida	N	Mean	Std. Deviation	t	P Value	significance
Pre treatment	Primi	168	2.13	0.62	0.35	0.73	p>.05
	Multi	33	2.09	0:58			
Post treatment	Primi	168	5.79	0.88	2.81	0.01	p <.05
	Multi	33	6.24	0.66			

Table 5. Improvement in Bishop's Score According to Parity

There is no significant difference in the pretreatment Bishop's score between multi and primi. There is significant difference in the post treatment Bishop's score between primi and multi, which shows multi achieved more score than primi.

Post treatment Bishops Score	Mode of Delivery						
	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							

Table 6. Correlation of Mode of Delivery with Post Treatment Bishop's Score

Out of the 156 patients with favourable Bishop's score, 127(81.4%) delivered normally, 22 required lower segment caesarean section (LSCS) (14.1%) and 7 (4.48%) delivered with the help of vacuum/forceps. Out of the 45 patients who failed to achieve favourable Bishop's score required PGE1 for ripening and 27 (60%) delivered normally, 15 (33.3%) required LSCS and 3(6.7%) delivered with help of vacuum/forceps. The observed differences are statistically significant.

	EASI Duration Frequency			BS>=6	
	Duration	Frequency	Percent	No.	%
EASI Expulsion	<12hrs	75	37%	64	31.8%
	>12 and < 24 hrs	46	22.8 %	40	19.9%
EASI Removal	Before 24 hrs	Nil	Nil	Nil	Nil
	At 24 hrs	80	40%	52	25.8 %
	Total	201	100.00%	156	

Table 7. EASI Duration and Bishop's Score

In 75 patients (37%), catheter expelled off their own before 12 hrs. Of this 64 patients (31.8% of total), achieved favourable Bishop's score before 12 hrs. In 46 patients (23%), catheter expelled off between 13-24 hrs. Of this, 40 patients (19.9%) have achieved favourable Bishop's score. In 80 patients (40%), catheter was removed after 24 hrs. and of this 52 patients (25.8%) achieved favourable Bishop's score (≥6).

Mode	Frequency	Percent
Normal	154	76.6%
Instrumental	10	5%
CS	37	18.4%
Total	201	100%

Table 8. Mode of Delivery

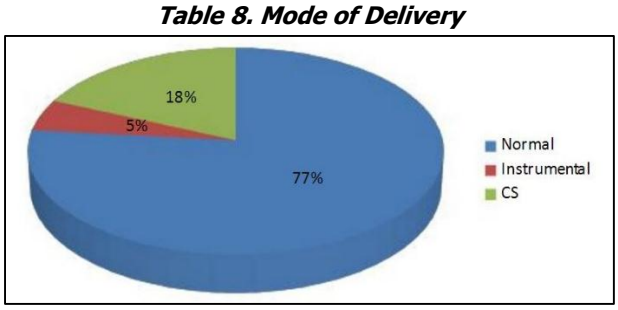

Figure 4. Mode of Delivery

Maximum patients 154 (76.6%) delivered vaginally. 8 patients required vacuum and 2 patients required forceps and in 37 (18.4%) patients, lower segment caesarean section was done. Out of the 154 patients, 53 patients (34.49%) delivered within 24 hrs. from the starting of ripening and 101 patients (65.51%) delivered within 24-48 hrs. from the starting of ripening with a mean EASI - Delivery interval 26.92 hrs. and the mean induction delivery interval was 11.10±6.02 hrs.

Indications	Frequency	Percent	BS>=6	BS<6
NRFHR	15	7.5	10	5
Failed Induction	12	6.0	3	9
Thick MSAF	4	2.0	4	0
Protracted Active phase	3	1.5	3	0
Cord prolapse	1	5	1	0
Failed Trial-CPD	1	.5	1	0
Abruption Grade-2	1	.5	0	1
Total	37		22	15

Table 9. Indications for Caesarean Section and Post Treatment Bishop's Score

The main indication for CS was NRFHR (7.5%) followed by failed induction (6%). In 22 cases, out of the 37 cases of CS, oxytocin augmentation was done and in 15 cases PGE1 was used as a second ripening method. Out of 15 cases of NRFHR, 10 cases were augmented with oxytocin where in 9 cases out of the 12 cases of failed induction, PGE1 was used as a second ripening method.

	Gravida	N	Mean	Std.Deviation	t	p Value
IDI-	Primi	167	11.77	6.22	3.64	0.00
	Multi	33	7.71	3.23		

Table 10. Induction Delivery Interval Based on Parity

There is a significant difference in the mean score of primi and multi as regard to induction delivery interval (p value <0.05), which shows that multipara have shorter induction delivery interval.

	GAin days	N	Mean	Std. Deviation	t	p value
Induction Delivery interval	Pre term	33	11.62	6.71	0.53	0.59
	term	168	11.00	5.90		

Table 11. Induction Delivery Interval Based on Gestational Age

The induction delivery interval did not differ significantly between term and preterm pregnancy when EASI is used as ripening agent (p>0.05).

New born APGAR score	Mean	N	Std.Deviation	t	P value
5 min	8.94	201	0.39	1.33	0.18
1 min	8.85	201	1.07		

Table 12. Neonatal Outcome

The mean Apgar score at 1 minute and 5 minutes did not differ significantly (p value >0.05).

Maternal Complications

There were no cases of febrile illness, vaginal bleeding, altered presentation, chorioamnionitis and postpartum endomyometritis in the current study.

DISCUSSION

Analysis of maternal age of the study group showed that 42.8% of the subjects were of the age group 26 to 30 years. The study included both primigravida (83.6%) and multigravida (16.4%). The gestational age ranged from 32 weeks 6 days to 40 weeks 4 days with 77.6% term and 22.4% preterm cases. All cases included had an unripe cervix with Bishop's score 4. The study included all cases of EASI during the study period including preterm cases also. The mean pretreatment Bishop's score was 2.125±0.609, 75.6% were having Bishop's score 2. Improvement in Bishop's score in the present series 156 patients achieved Bishop's score 6 after EASI. Of this 64 (31.8%), patients achieved Bishop's score 6 before 12hrs., 40 patients achieved Bishop's score 6 between 12hrs. and 24 hrs. and 52 patients achieved Bishop's score 6 at 24 hrs. Rouban and Arias[1] had similar results in their studies. 37% of women who received extra amniotic saline infusion achieved Bishop score of 8 or more at 8 hrs. compared with 14% who received prostaglandin. Schreyer et al in a controlled trial reported that cervical ripening was achieved in all 52 women in whom extraamniotic saline was used.

There was no significant difference in the pretreatment Bishop's score in primigravida and multigravida. However, there was significant difference in the post treatment Bishop's score in primi and multigravida with higher mean post treatment Bishop's score in multigravida ($p<0.05$). In the present study, 76.6% of patients achieved vaginal delivery within 48 hours, 34.49% delivered within 24 hours and 65.5% delivered within 24-48 hours with a mean EASI deliveryinterval of 26.92 hours. Jens Lyndrup in his randomised comparison of BCEAS with PGE2 vaginal pessaries reported that vaginal delivery achieved within 48hrs.by BCEAS in 62% of patients as compared with 78% by vaginal PGE2 pessary. In another two previous studies, using the same vaginal PGE2 pessary on similar patients, 72% and 74%, respectively were delivered vaginally within48 hrs. The result of the present study shows that ripening with EASI results maximum vaginal delivery. In a comparative study, Sujatha et al observed that more women had spontaneous vaginal delivery (80%) in Foley group than misoprostol (59.28%) and dinoprostone group (70.15%).[2] In the present study, the overall caesarean delivery rate was 18.4%, which is less than that observed by Karjane et al 2006,[3] i.e. 21.2% and 20.1% with EASI and with Foley alone. Rate of CS in patients who achieved favourable Bishop's score is14.1%, whereas in those who required PGE1 for ripening the CS rate was 33.3% Ghanei et al (2009)[4] in their study observed that CS rate is higher (28.8%) with EASI than with Foley alone (24.6%). He explained that the reason could be characteristic of the assigned population - all patients being nulliparous.

In another study, AS Zafarghandi et al (2004)[5] observed that CS rate was 18.18% with extraamniotic saline infusion compared with 9.1% with extraamniotic infusion with corticosteroids Sujatha et al (2012)[2] in her study observed that the CS rate was 18% with Foley catheter, which is lower than with misoprostol (29.63%) and dinoprostone (23.07%). The overall CS rate in the study was comparable with the reported studies. In the current study, CS due to failed induction were 5.9% (12 cases), 7.46% (14cases) due to foetal distress, which were not attributed directly to EASI, because all these cases were after spontaneous expulsion of EASI or removal after 24 hrs. No case of hyperstimulation was reported during EASI period, so NRFHR was also not attributed to EASI.

In the 45 patients who required PGE1 as a second ripening agent, 26 delivered normally, 15 delivered by CS and 4 delivered by forceps/vacuum. Of the 156 patients who achieved favourable Bishop's score, 19 progressed with ARM only. 137 patients (87.8%) required oxytocin induction or augmentation.

Out of the 19 patients, 17 delivered vaginally and 2 cases required LSCS. Of the 137 patients who required Pitocin augmentation, 111 patients delivered vaginally and 20 cases required CS and 6 cases delivered with vacuum/forceps. Overall, CS rate was 18.4 and instrumental delivery was 4.87%. CS rate in those patients who achieved favourable Bishop's score with EASI was 14.1% and instrumental delivery was 4.4%. In those patients who required PGE1 as a second ripening method, the CS rate is 33.33% and instrumental delivery 6.6%.

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

The mean induction delivery interval in this study was found to be 11.02±6.10 hrs., which is similar to that found by Ghanaei et al (2009).[4] The EASI delivery (start of ripening to delivery) interval was 26.92±9.40 hrs. This is similar to that found by Goldman et al[6] - (25.9 hrs.). In the present study, comparing the induction delivery interval in primi and multi, there is significant difference in the mean induction delivery interval ($p<0.05$) with 7.71 hrs.in multi and 11.77 hrs. in primi. There was no significant difference in the induction delivery interval with regard to term and preterm cases.

Sujatha[2] et al (2012) in their study observed shorter induction delivery interval with Foley's catheter (19.18±2.12) than with misoprostol (21.04±2.32) and dinoprostone (20.12±1.21 hrs.). In present study, IDI is shorter than that observed by Sujatha et al.[2]

Karjane NW (2006)[3] in a comparative study of transcervical Foley bulb with and without EASI for induction of labour reported that time from induction to vaginal delivery was 16.58(±7.55) hrs.in EASI group compared to 21.47(±9.95) hrs. in the Foley's group. The induction delivery interval in this study was found to be shorter than the reported studies.

The overall neonatal outcome was favourable in this study. In this study, 3.4% of the babies had Apgar score less than 7 at 1 min. and 0.99%(2 babies) had low Apgar at 5 (both these babies were early neonatal death and born by LSCS). This finding was much more favourable than reported by Ghanaei et al (2009)[4] where 6.8% babies had Apgar score <7 at 1 min. and 1.36% had low Apgar at 5 mins.

In a comparative study with transcervical Foley's bulb with and without EASI reported that the mean Apgar score at 1 min. and 5 mins. were 9 in both group.

Mariyam Kashnian (2008) in a comparative study of EASI alone with EASI and dexamethasone reported that 5.3% neonates had Apgar <7 at 5 mins. and 5.3% SCNU admission.

In the current study, there were 25(12.4%) admission in SCNU. This is slightly higher than the published studies. In most of the reported studies, study group included term pregnancy, whereas in the present study, all cases of EASI during the study period was taken, which included 22.4% preterm pregnancy.

Most published studies reports the relative efficacy of EASI compared to other mechanical and biochemical ripening agents mainly prostaglandins 1 and 2. Due to lack of large trials, published data on complications of EASI induction are less. Karjane NW (2006)[3] reported that chorioamnionitis occurred in 4 of 66 (6.1%) women with

EASI. Also, reported that adverse events were rare and unrelated to method of inductions.

The main complication encountered in women undergoing EASI were Sharon Maslovitz (2009),[7]acute transient febrile reaction, chorioamnionitis, NRFHR, vaginal bleeding, etc.

Schreyer et al[8] reported mild bleeding (6%) shortly after catheter insertion and Sherman et al reported rupture of membrane at the time of catheter insertion (2%).

Kassam Mahomed et al (1997)[9] reported that there was no evidence of increase in febrile morbidity from extraamniotic saline. Mandana M Ghanaei (2009)[4] reported that the risk of chorioamnionitis was 6.9% in the EASI group and 8.2% in Foley group alone.

In the published studies, prophylactic antibiotics was given only in cases of group B streptococcus prophylaxis or when indicated clinical chorioamnionitis. In the current study, prophylactic broad-spectrum antibiotic were given half an hour before the procedure for all the patients. There were no cases of febrile illness, chorioamnionitis or postpartum endomyometritis in the present study.

CONCLUSION

EASI was an effective method for cervical ripening. EASI do not induce painful uterine contraction, which make it an ideal ripening agent and increases the need for oxytocin induction or augmentation. Cervical ripening with EASI resulted in successful induction with maximum number of vaginal delivery, shorter induction delivery interval and lower caesarean rate. Cervical ripening with EASI results in shorter induction delivery interval. Caesarean rate was low with EASI ripening. EASI can be used as the ripening method in areas with limited resources. EASI is safe, easily available, simple, reversible and not very expensive and no refrigeration is needed. With the use of prophylactic antibiotics, the safety can be increased. It is well tolerated by women and there were no systemic and serious side effect.

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