ORIGINAL ARTICLE

COMPARATIVE STUDY OF INTRA UTERINE FOLEY'S CATHETER WITH OR WITHOUT SALINE INFUSION FOR CERVICAL RIPENING AND INDUCTION OF LABOUR

Jameela C[1]

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ABSTRACT: OBJECTIVE: To compare transcervical Foley catheter with or without extra amniotic saline infusion for induction of LABOUR patients with an unfavorable cervix and also to determine safety of both the methods. **METHOD**: 50 patients were randomly selected & grouped into two categories of 25 each. Group a was induced with foley's catheter alone & group b with foleys with extra amniotic saline infusion. After induction of labour, labour was augmented with arm or oxytocin after expulsion of the catheter. Antibiotic was not prescribed. The primary outcomes were induction to delivery interval, incidence of chorioamnionitis & improvement in the bishop score. The secondary outcomes were mode of delivery, apgar score at 1 & 5 minutes and NICU admissions. **RESULTS:** 50 women were included in this study, 25 in each group. Baseline demographic characteristics including age, parity, gestational age at induction, pre-induction Bishop Score, indications for induction were comparable between both groups. The mean induction - delivery interval in extra amniotic saline infusion group was 11.2 hrs. While that in the Foley group was 11.46 hrs. ($p>0.05$). There was no statistically significant difference between the groups in change in the Bishop Score; however each individually improved the Bishop score significantly. The cesarean rate was not statistically different in the groups ($p=0.569$). There were no neonatal morbidities and no evidence of chorioamnionitis in any of the patients.
CONCLUSION: In women with unfavorable cervix, addition of extra amniotic saline did not improve the efficacy of labor induction, although both methods are safe for labor induction.
KEYWORDS: Transcervical Foley, Extra Amniotic Saline Infusion, Induction of Labor.

INTRODUCTION: In the course of normal Labour, softening and dilatation of the Cervix is the result of a complex of biochemical reactions which makes the cervix hydrophillic resulting in a favourable cervix. In absence of these changes, cervix needs to be ripened by artificial means. Induction of labor is initiation of labour by artificial means prior to its spontaneous onset at viable gestational age, with the aim of achieving vaginal delivery. Its success is largely dependent on the state of the Cervix whose favorability is assessed using the Bishop Score.[1] Patients with a Bishop score of 4 or less require cervical ripening before induction of labor.[2]

Techniques to ripen the Cervix artificially before labor induction shorten the course of labor and improve the chances of a successful vaginal delivery.[3] Ripening of the Cervix may be achieved by mechanical techniques[4-8] as well as by pharmacological agents.[8-12] One of the mechanical methods of cervical ripening is transcervical Foley catheter insertion. Another method is adding extra amniotic saline infusion via the[13]

The purpose of this study is to find out whether addition of Extra Amniotic Saline Infusion (EASI), increases the success rate without adding to safety concerns of simple Foley catheter insertion for cervical ripening and labor induction.

AIMS AND OBJECTIVES:

1. To compare, Transcervical Foley catheter, with and without extra amniotic saline infusion, for induction of labor, in patients with unfavourable cervix w.r.t

Primary outcome measures were Induction-to- delivery time (Foley insertion to delivery interval), Incidence of chorioamnionitis (defined as intrapartum temperature 100.4° F without evidence of extra uterine source) & improvement in Bishop Score.

Secondary outcome measures were; mode of delivery, Apgar at 1 & 5 minutes & NICU admissions.

MATERIALS AND METHODS: This study was conducted at Father Muller Charitable Institution's Hospital, Mangalore. Data was collected from patients in Obstetrics and gynecology department from 01-01-2007 to 30-08-2008. All pregnant women admitted to labor ward were evaluated for eligibility, which included thorough history, fetal status, through examination including PV examination to determine the Bishop Score. Eligible women were explained about the procedure. Written & informed consent was obtained. 50 pregnant women were randomized into two groups. First 25 patients were assigned to the Foleys with EASI and next 25 were assigned to Foley alone.

Inclusion Criteria: Singleton pregnancies irrespective of parity, pregnant women with adequate pelvis, bishop score of less than 4.

Exclusion Criteria: Patients with significant vaginal bleeding, Severe local infection. Patients in spontaneous labor, Patients with severe CPD, malpresentations and Patients with previous LSCS.

PROCEDURE: Once the patients were assigned, procedure was explained, consent taken they were given a dorsal lithotomy position. The vaginal cavity was cleansed with betadine solution. The cervix was visualized by inserting a Sims speculum to retract the posterior vaginal wall and the anterior vaginal wall was retraced by an anterior vaginal wall retractor. The anterior lip of the cervix was held with a sponge holding forceps to stabilize it. Under direct. Visualization a No 16 Foley catheter was inserted through the cervical canal extra amniotically using an Artery forceps to push it through. Once the balloon has passed beyond the internal Os, it was inflated with 40cc distilled water. The catheter was then pulled back against the internal Os and was taped to the medial aspect of the thigh with minimal traction.

In women assigned to EASI, 350 cc warm normal saline was introduced through the catheter port over 20 min and a knot was put at the distal end to prevent the saline from escaping and then strapped to the medial aspect of the thigh with minimal traction.

Post insertion FHR was checked and a heart rate tracing was recorded. Patient was then observed for the vitals, uterine activity, and fetal heart rate hourly & Spontaneous expulsion of the catheter. If the catheter did not expel spontaneously at the end of 12hrs, it was manually removed. On occurrence of any fetal heart rate abnormality the catheter was removed and patient was taken up for cesarean section. When the Foleys catheter was expelled spontaneously or removed manually the cervix was evaluated and if the Bishop score was favorable, labour was augmented with arm or oxytocin depending on the case. Antibiotic coverage was not given to the patients unless there were any signs of infection. Cesarean delivery was performed at discretion of the On-duty doctor. For the purpose of analysis, failed induction was defined as labor arrest before 3 cm of cervical dilatation. Failure to progress was defined as secondary arrest of labor at or beyond 3 cm dilatation despite adequate uterine contractions for a minimum of 2 hrs.

Data was analyzed by chi-square, Mann- Whitney U test and Fischer exact test.

RESULTS: A total of 50 women were included in this study. These women were for induction of labor for various indications. To avoid any bias, first 25 women were induced by transcervically introduced Foley catheter with extra – amniotic saline infusion and the next 25 women were induced by transcervical Foley alone. Both the group were comparable in characteristics such as.

1. Age,
2. Parity,
3. Gestational ages at induction,
4. indication for induction,
5. Pre-induction Bishop Scores,

1. Age of the patient: The age of the patients in the Foley with EASI group was 23.08 yrs while that in the Foley group was 23.68 yrs. Thus the groups were comparable.

2. Parity: The percentage of nulliparous patients were 56% in Foley with EASI and 68% in the Foley group. There was no statistical difference in this variable, thus the groups were comparable.

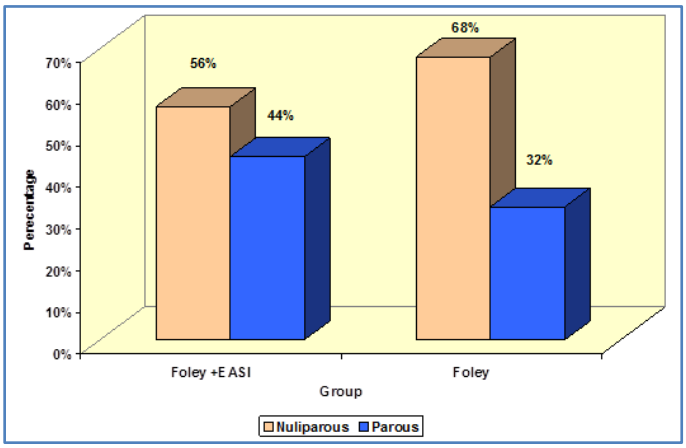

Fig. 1: Parity

a. x2=1.333, p= 0.248 ns

3. Gestational ages at induction: Mean Gestational Age at induction in Foley with EASI group was 39.1wks while that in the Foley group was 38.8 wks., thus were comparable.

Group	n	Mean	Std. Deviation	t
Foley + EASI	25	39.1840	1.898622	0.6270 p= 0.534
Foley	25	38.8840	1.470737	

4. **Indications for induction:** The indications for inductions in both groups were similar, and were gestational hypertension, severe preeclampsia, Postdates, severe IUGR, IUD, thus the groups were comparable.

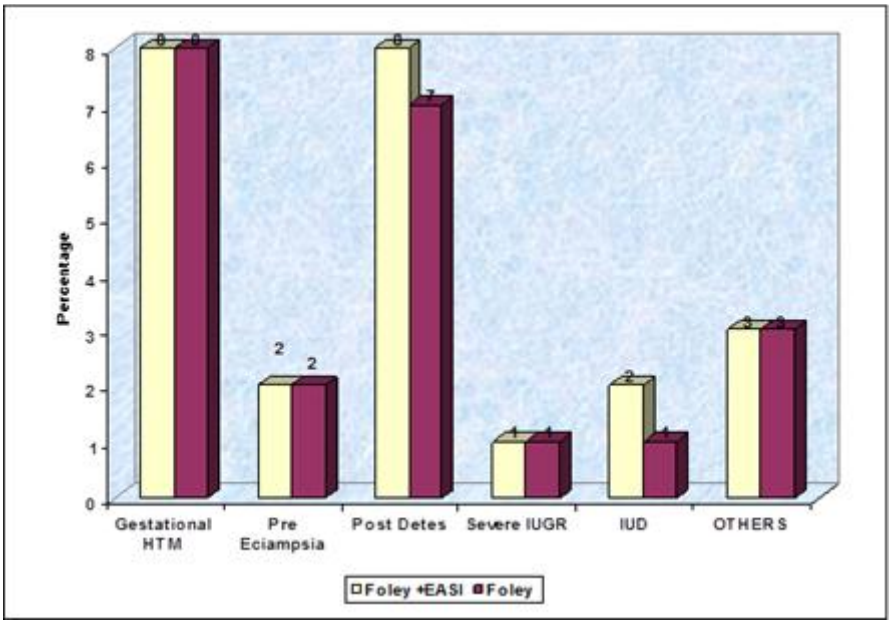

Fig. 2: Indications for Induction

Z=0.54300, p=0.534

5. Pre Induction Bishop Scores:

Group	N	Mean	Std. Deviation	Z
Foley + EASI	25	2.4	0.81650	p>0.05
Foley	25	2.2	0.81649	

Both the groups were comparable.

There was no statistical difference noted in the

1. Mode of catheter expulsion,
2. Change in Bishop Score,
3. Mode of delivery
4. Neonatal out come
5. Maternal Morbidity

1. **Catheter Expulsion:** The percentage of manual versus spontaneous expulsion was 24% vs. 76% in Foley with EASI and 8% vs. 92% in Foley group. Statistically there was no difference in the method of expulsion.

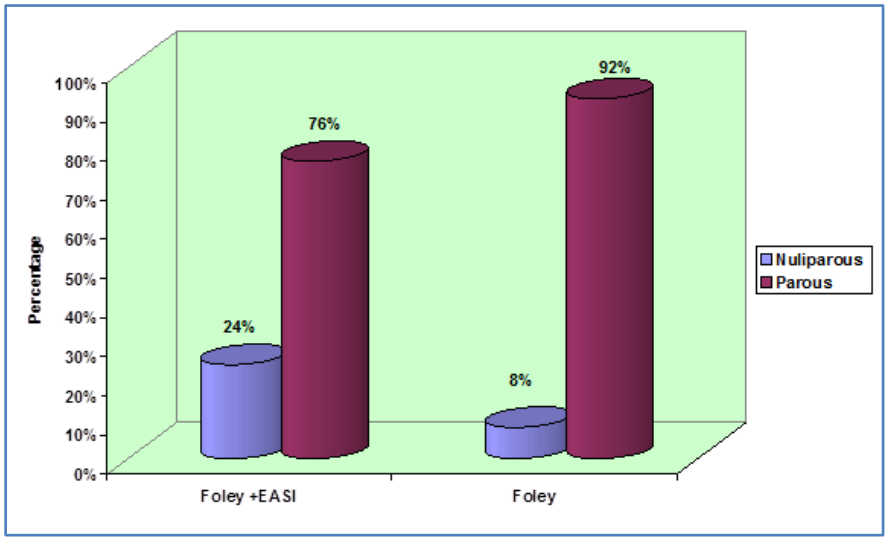

Fig. 3: Percentage of expulsions

Ax2=2.168 p=0.141 na

2. The Change in Bishop Score: The change in each individual group was highly significant but the change compared between the groups, Foley with EASI and Foley, was not significant.

P GROUP		Paired Differences		z	P
		Mean	Std. Deviation		
Foleys + EASI	BS Pre - BS Post	-4.3600	1.19304	4.412	.001
Foleys	BS Pre - BS Post	-3.6800	1.18039J	4.417	.001

Table No. 3: The change in Bishop Score in individual groups

BS Pre - Pre induction Bishop Score
BS Post - Post induction Bishop Score

3. Change in Bishop Score, between the groups

Group	N	Mean	Z
Foleys+EASI Foleys	25 25	4.3600 3.6800	1.46100 p=0.144 ns
Table No. 4: Change in Bishop Score			

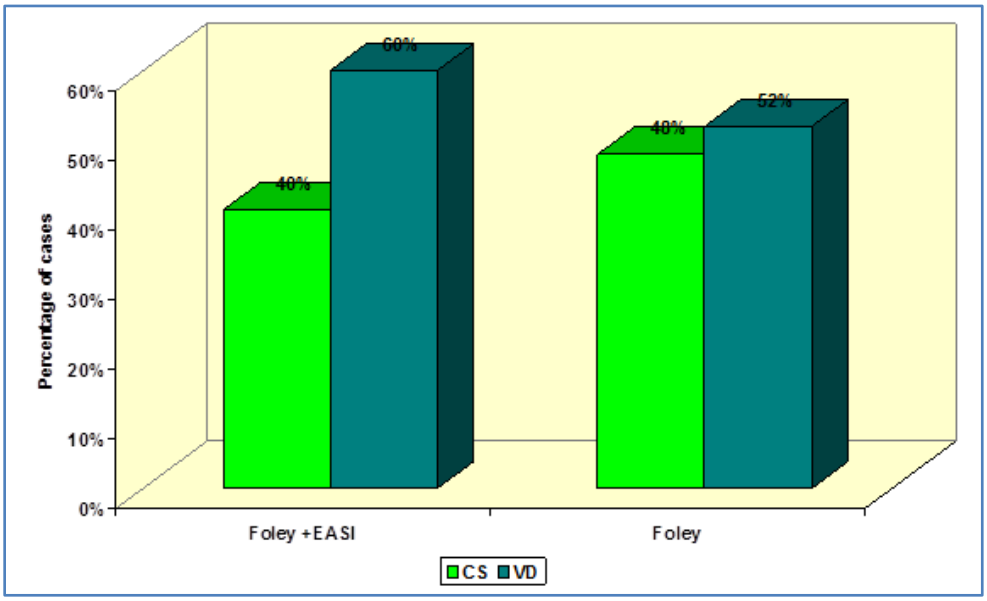

Fig. 4: Mode of Delivery

p=0.569 ns
VD - Vaginal Delivery
CS - Cesarean Section

4. Indications for Caesarean Section:

The indications for Cesarean deli very in the groups were:

- Failure to progress
- Fetal distress
- Cord presentation

Others, which included deteriorating renal functions in a case of severe Pre-Eclampsia, scar tenderness.

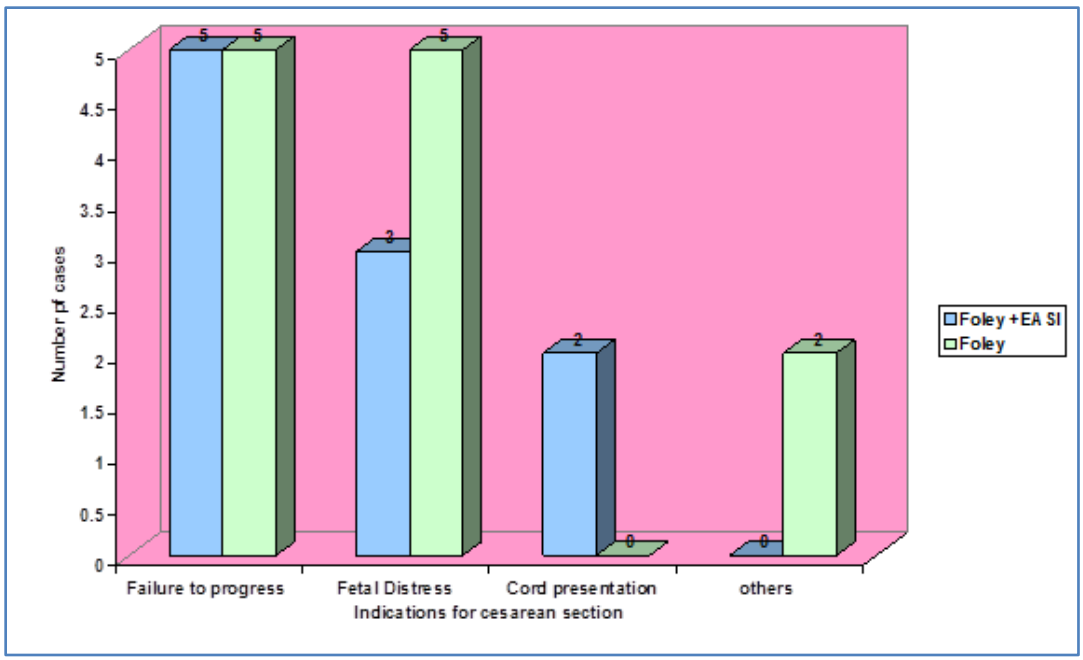

Fig. 5: Indications for Caesarean Section

a. x2 =3.254, p = 0.661

5. Neonatal Outcome: The neonatal outcome in terms of meconium in the liquor, occurrence of fetal distress indicated by type 2 decelerations in labor, birth weight of the babies and the Apgar scores is shown as below. No statistical difference in the groups.

	Foley with EASI n=25	**Foley n=25**	Z
Meconium in the liquor	3	2	p>0.05
Fetal distress	4	5	p>0.5
Birth weight(kg)	2.77	2.57	1.4.800 p=0.159
Apgar 1 min 5 min	7.9130 8.9130	7.7083 8.8750	0.33000 p=0.741 0.02200 p=0.982

Table No. 6: Neonatal Outcomes

The NICU admissions: Were one in each group which was just for observation and both babies were shifted to the mother's side in a couple of days. No neonatal morbidity or mortality seen.

			group		Total
			Foleys + EASI	Foleys	
	No	Count %	22 95.7%	23 95.8%	45 95.7%
	Yes	Count %	1 4.3%	1 4.2%	2 4.3%
Total		Count %	23 100.0%	24 100.0%	47 100.0%

Table No. 7: NICU Admissions

a. **p=1 ns**

Yes / No – in reference of NICU admission.

6. Maternal Morbidity:

- There was not a single case of Chorioamnionitis seen in any of the cases in both groups in spite of no antibiotic coverage offered.

DISCUSSION: In this randomized study, .the mean age of the candidates in our study was 23.08 yrs in EASI and 23.68 yrs in the Foley group, while that in the Karjane study[14] was 25.6 yrs in EASI and 25.1 yrs in the Foley group, in Lin Monique study[16] it was 25.3 in EASI and 25yrs in the Foley group. The percentage of nulliparous patients in our study was 56% in EASI and 68% in the Foley group (p=0.24), that in the Karjane study[14] was 51.5% in EASI and 51.4% in the Foley group (p=0.98), that in Lin Monique study[16] was 57% in EASI and 58% in the Foley group (p=0.48) whereas that in the Guinn study[15] was 58% in EASI and 49% in the Foley group (p=0.32).Thus, we had the maximum number of nulliparous patients in our study, may be the reason of the discrepancy in results when compared to the Karjane study.[14] Parous patients included third gravida to fifth gravida. The mean gestational ages in our study were 39.232 in EASI and 38.84 in the Foley group (p=0.534), whereas in Karjane study they were 39.6 in EASI and39 in the Foley group (p=0.71), Guinn study[15] they were 39.5±1.9 in EASI and 39±2.6 in the Foley group (p=0.34), while that in the Lin Monique study[16] they were 38.6±2.9 in EASI and 39±4.5 in the Foley group (p=0.55).

The indications for induction in our study were:

Table No. 8: Indications for induction (our study)

indications	EASI n=25	Foley n=25	P
Gestational HTN	8(32%)	8(32%)	0.587
Post Dates	9(36%)	7(28%)	
Severe PE	2(8%)	2(8%)	
Severe IUGR	1 (4%)	1(4%)	
IUD	2(8%)	1(4%)	
Others	3(12%)	6(24%)	

Others included trial of labor at 40 wks. in a low risk patient (2) GDM (l) in the EASI group and Non immune hydrops fetalis(l), Oligohydramnios^), trial of labor in a low risk patient at 40 wks.

The indications in the Guinn study[15] were:

Table No. 9: Indications for induction (Guinn[15] study)

Indications	EASI n=51	Foley n=49	P
Pre Eclampsia	13(22%)	9(18%)	0.56
Oligohydramnios	14(29%)	15(31%)	
Post term	13(27%)	14(29%)	
Diabetes	3(6%)	5(10%)	
Others	8(17%)	6(12%)	

These groups were also comparable.

The indications for induction in the Lin Monique trial[16] were:

Table No.10: Indications for induction (Lin Monique[16] Study)

Indications	EASI n=97	Foley n=91	P
Pre Eclampsia	41(42.3%)	41(45.4%)	0.70
Post mature	28(28.9%)	20(22%)	0.28
Oligohydramnios	25(25.8%)	20(22.2%)	0.54
Intrauterine fetal growth restriction	6(6.2%)	13(14.3%)	0.07
Abnormal antepartum testing	6(6.2%)	7(7.7%)	0.68
Others	16(16.5%)	14(15.4%)	0.84

There were no statistical differences and thus the groups were comparable.

The pre-induction Bishop score in our study was 2.4 in the Foley with EASI and 2.2 in the Foley group. It was 3 in both the groups in the Karjane study,[14] 3.3 in the Foley with EASI and 3.7 in the Foley grouping the Guinn study,[15] while it was 3 in the Foley with EASI and 2 in the Foley group in the Lin Monique study.[16] Statistically these parameters were similar, thus the groups were comparable in all the studies. But our study had the lowest Bishop score when compared to the others, which could be the cause of differences in the results. Considering the results our study showed no statistical difference between the mode of catheter expulsion, which was 24% manual and 76% spontaneous in the Foley with EASI group and 8%manual and 92% spontaneous in Foley group (p=0.141).The other groups have not compared this parameter.

Table No.11: Indications for induction (Karjane [38] Study)

Indications	EASI n=66	Foley n=74	P
Gestational HTN	30	32	> 0.05
Impending Post dates	11	19	
Oligohydramnios	11	12	
Intrauterine fetal growth restriction	5	2	
GDM	2	1	
Others	7	8	

There were no statistical differences and thus the groups were comparable.

The pre-induction Bishop score in our study was 2.4 in the Foley with EASI and 2.2 in the Foley group. It was 3 in both the groups in the Karjane study,[14] 3.3 in the Foley with EASI and 3.7 in the Foley grouping the Guinn study,[15] while it was 3 in the Foley with EASI and 2 in the Foley group in the Lin Monique study.[16] Statistically these parameters were similar, thus the groups were comparable in all the studies. But our study had the lowest Bishop score when compared to the others, which could be the cause of differences in the results. Considering the results our study showed no statistical difference between the mode of catheter expulsion, which was 24% manual and 76% spontaneous in the Foley with EASI group and 8% manual and 92% spontaneous in Foley group (p=0.141). The other groups have not compared this parameter. The change in Bishop Score was very highly significant in both groups but was comparable to each other. The post induction bishop Score were however more favorable in cases of Foley +EASI (>8) as against Foley alone (>4 but <7). The other studies haven't considered this parameter as well. The Guinn study has however considered the dilatation at insertion of the epidural catheter which was not significantly different in the groups.

The Cesarean delivery rate was high in our study in both the groups (around 40%), but the indications for Cesarean Section were most often failure to progress due to mal positions (deflexed head, DTA) and CPD detected after trial of labor. There were no cases of failure of induction. There was one case of abruption with fetal distress which developed in the course of labor. Fetal Distress were seen in 4 out of 25 in EASI group and 5 out of 25 in Foley group, which was

higher than that seen in the Guinn study[15] where 2 out of 51 in EASI group and 3 out of 49 in Foley group had Fetal distress. There was no significant difference between the Cesarean delivery rates in both the groups as in the study by Lin Monique[16] as well as Karjane.[14] The occurrence of meconium in liquor in our study was in 8% of the cases was same as in other studies, 3 out of 25 in the EASI group and 2 out of 25 in the Foley group in our study, 7 out of 51 in EASI and 8 out of 49 in Foley group in the Guinn study,[14] 8 out of 97 in EASI and 10 out of 91 in Foley group in Lin Monique study.[16]

The Average birth weights in our study were 2.77 in EASI and 2.57 in the Foley group (p=0.159). They were 3.085±553 in EASI and 3.088+531 in the Foley group in the Karjane study[13] (p=0.98), 3±0.8 in EASI and 3±0.7 in the Foley group in the Lin Monique study[16] (p=0.81) The Apgar Scores at 1 min (8) and 5 min (9) were equal in both groups as were in the Karjane,[14] Guinn[15] and the Lin Monique[16] studies. However there was one NICU admission in each group with no serious morbidity and no mortality in our study where as the Guinn study[15] had 6 out of 51 in EASI and 6 out of 49 in Foley, while the Karjane study[14] had a case of neonatal sepsis in Foley group.

We did not administer antibiotics routinely to our patients and there was not a single case of chorioamnionitis in our study. In the Lin Monique study[16] they administered antibiotics to more than half of their patients and had around 8% cases in each group. In the Guinn study, the rate of chorioamnionitis was 10% in EASI group and 12% in Foley group, while the Karjane study[14] showed higher rate of chorioamnionitis in the Foley group 16.2% against 6.1% in the EASI group. In spite of this our and the rest of the studies refute the findings of a retrospective study by Levey and coworkers,[13] of increased rate of chorioamnionitis in the cases induced with a Foley catheter compared to other methods of labor induction.

In all the studies the Foley after placement was removed after 12 hours if not expelled spontaneously and FHR was regular. But in all except our study, oxytocin was started concurrently with Foley with or without EASI. We started oxytocin only after expulsion of the Foley along with ARM whenever favorable. We observed that the patient not only showed improvement in the Bishop Score but also there was establishment of some uterine activity which was further augmented by ARM and Oxytocin drip. Few patients in the Guinn study[15] in whom the catheter placement failed initially were administered prostaglandins intracervically and once their crevices began to dilate Foley were inserted. We had no cases with failure of placement.

The differences between our method and that of the others were in the rate of saline infusion, at the rate of 30 ml/hr. in Guinn study[15] and Lin Monique study[16] and 40 ml/hr. in the Karjane study[14] whereas we infused saline at a much faster rate 350 ml over 20 min. Also the balloon size differed, 30 ml in Guinn[15] and Lin Monique study,[16] 50 ml in Karjane study[14] and 40 ml in ours. As the Foley bulb size can also affect the labor induction efficacy,[17] this can be the cause of the differences. But since the same balloon size was used in both groups in all of the studies this should not cause the differential effect. In the Guinn study,[15] Lin Monique study[16] and our study the catheter was taped to the inner thigh with minimal traction while in the Karjane study[14] no such tension was applied. Thus the application of traction does not add to the effect of the Foley bulb.

Although the efficacy of Foley and Foley plus EASI is thought to be largely due to its mechanical effects on the cervix to promote cervical ripening, cytokine release that occurs while the balloon is inflated also has a role to play.[18] In theory extra amniotic saline may lead to cytokine release on a larger scale than Foley alone, these cytokines might get diluted by the saline thus attenuating its effect thus similar results in both groups. Our data indicates that addition of extra amniotic saline infusion to transcervical Foley catheter does not have any effect on the induction delivery interval, 11.2 hrs. In EASI group while 11.46 hrs. in Foley group (p=0.609).This is in agreement with the study by Guinn and coworkers as well as that by Lin Monique et al4 as opposed to the study by Karjane and coworkers,[14] who found a beneficial effect with addition of EASI. However the trial by Karjane and colleagues[14] reported a difference in induction to vaginal delivery interval. Such a measure is likely to be biased because the exclusion of women who underwent a cesarean delivery unbalances the groups with respect to unknown cofounders and clouds the interpretation of the data from this trial. In an analysis of all patients who delivered, randomization will theoretically balance unknown cofounders, whereas analysis of only those that delivered vaginally is subject to confounding and is at a higher risk of a type I error. In our study the induction to vaginal delivery time was 10.81 hrs. in the Foley with EASI group, whereas it was 11.38 hrs. in the Foley group. 'There was no significant statistical difference in the groups though.

SUMMARY: In this interventional study, done on 50 patients who were divided into 2 groups, first 25 candidates were assigned to Foley with EASI as a form of cervical ripening and labor inducing agent while next 25 candidates were assigned to Foley alone for the same.

- Mean age of the patients were 23 yrs. in both groups
- Nulliparous patients included in the group were 56% in Foley with EASI and 68% in Foley group.
- Mean Gestational age at induction was 39 wks. In Foley with EASI and 38 wks. in the Foley group.
- Mean Pre-induction Bishop Score was 2.4 in Foley with EASI and 2.2 in Foley group.

At the completion of the study the following was noted,

- Addition of extra amniotic saline infusion to transcervical Foley catheter does not shorten the induction delivery rate.
- EASI improves the Bishop score significantly, as does Foley alone.
- EASI can be used safely in patients with medical complications, patients with previous cesarean delivery.
- EASI does not increase the cesarean delivery rate.
- EASI as well as transcervical Foley do not increase neonatal or maternal morbidity rate.

CONCLUSION:

- In women with unfavorable cervix, addition of extra amniotic saline does not improve the efficacy of labor induction.
- Both methods are equally safe methods for cervical ripening and labor induction.

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AUTHORS:

1. Jameela C.

PARTICULARS OF CONTRIBUTORS:

1. Associate Professor, Department of Obstetrics and Gynaecology, Fr. Muller Medical College Hospital.

NAME ADDRESS EMAIL ID OF THE CORRESPONDING AUTHOR:

Dr. Jameela C,
Department of Obstetrics and Gynaecology,
Fr. Muller Medical College Hospital,
Kankanady, Mangalore – 2.
E-mail: jkhilar38@yahoo.com

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