



ISSN (P): 2522-6614  
ISSN (E): 2522-6622  
© Gynaecology Journal  
[www.gynaecologyjournal.com](http://www.gynaecologyjournal.com)  
2024; 8(1): 01-08  
Received: 04-10-2023  
Accepted: 07-11-2023

**Dr. Suchitra Somkuwar**  
IVF Consultant, Indira IVF,  
Jabalpur, Madhya Pradesh, India

**Dr. Satish Shetty**  
Senior Consultant, Civil Hospital,  
Dharwad, Karnataka, India

**Dr. Rupali Vaijunath Mungase**  
Senior Resident, SMBT Medical  
College, Nashik, Maharashtra,  
India

## **A prospective observational study on efficacy and safety of extra amniotic saline infusion with transcervical foley's catheter in induction of labour in post-dated pregnancy**

**Dr. Suchitra Somkuwar, Dr. Satish Shetty and Dr. Rupali Vaijunath Mungase**

DOI: <https://doi.org/10.33545/gynae.2024.v8.i1a.1408>

### **Abstract**

There are various methods available for ripening and induction of Labour. Induction of labour can produce risk of uterine hyper stimulation and rupture and fetal distress. The aim of this study is to evaluate the effectiveness and safety of foley's catheter with Extra Amniotic Saline Infusion. This was a prospective observational study conducted in the Department of Obstetrics and Gynaecology at District hospital Dharwad. Patients were selected after proper counseling and getting their consent. A total of 200 postdated antenatal women with bishop score of less than or equal to 6 taken up for this study. The induction-expulsion interval was 7 hours in the primigravidae and 6 hours in multigravida. Upon comparing with unpaired t test, the difference is statistically significant. 117 patients (58%) had a normal vaginal delivery. This was followed by 56 patients (28%) who had a caesarean section. The proportion of neonates who had a 5minute Apgar score of less than 6/10 was 17.5%. 36 neonates required NICU admission and all the neonates were discharged within 48 hours. Of this, 21 were discharged within 24 hours of admission. Extraamniotic saline infusion is a simple, inexpensive easily available method of induction.

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

### **Introduction**

Induction of labour [IOL] is an artificial initiation of labour before its spontaneous onset for the purpose of delivery of the fetoplacental unit [1]. It may be indicated despite an unripe cervix. When the cervix is unfavourable, as determined by the bishop pelvic scoring system, labour induction is associated with a higher incidence of prolonged labour and operative vaginal delivery and caesarean delivery due to failed induction and fetal distress. Under these circumstances agents for cervical ripening may be used to soften, thin out and dilate the cervix, in order to reduce the induction to delivery time and to decrease the likelihood of a failed induction [2]. Methods of induction of labour include pharmacologic methods (Misoprostol, Dinoprostone, oxytocin), and mechanical methods (Foley's catheter [FC], Double balloon catheter, Laminaria). Mechanical dilatation of the cervix is among the oldest methods used to induce labour among women with normal pregnancies. Agents that have been used include balloon dilators such as Foley's catheter. The trans-cervical Foley's catheter balloon placement was first described by Krause in 1853 and subsequently introduced to obstetric practice by Ezimokhai and Nwabineli in 1980 [3].

The use of intracervical Foley's catheter[FC] reduces the risk of uterus hyper tonicity and rupture in women with one caesarean section as the intracervical placement of Foley's catheter induces the cervical repining without inducing any uterine contractions [4, 5]. Other pharmacological agents prostaglandin [PGs] E2 (Dinoprostone) 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, diarrhoea 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 Extraamniotic saline infusion [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. It can be also used safely in patients with previous caesarean section for cervical ripening and induction of labour

**Corresponding Author:**  
**Dr. Suchitra Somkuwar**  
IVF Consultant, Indira IVF,  
Jabalpur, Madhya Pradesh, India

[6]. In advanced gestations EASI has historically been used in the context of pregnancy termination. Extra-amniotic saline is infused through a transcervical catheter, for the purpose of IOL in the third trimester. Infusion rates can vary between 30 and 60 ml/hour [7]. This results in stripping of the membranes with an increase in local PGs to induce labour [8]. Although chorioamnionitis and/or endometritis appear to be theoretical risks [9]. EASI was found to reduce the induction delivery interval when used in association with the Foley's catheter versus the Foley's catheter itself; however, other studies found no benefit to using EASI in combination with Foley catheters. The evidence for using EASI in association with PGs is similarly conflicting. With regard to induction delivery time, some studies have shown a benefit (3–5 hour reduction), while others have shown no effect. However, when used with PGs, EASI has been shown to improve cervical ripening scores in most studies. This does not, however, translate to reduction in induction-to-delivery intervals.[10] There are two main types of PGs used for IOL: PGE1 (oral or vaginal misoprostol) and PGE2 (tablets and gels, and a controlled-release preparation called dinoprostone).

The lowest caesarean section risk was associated with the use of a titrated low-dose oral solution (<50 micrograms) of misoprostol. Vaginal delivery within 24 hours of induction was most likely to be achieved when vaginal misoprostol tablet ( $\geq 50$  micrograms) was used; however, this effectiveness was associated with undesirable effects including an increased risk of adverse fetal heart changes and uterine hyperstimulation. Therefore, 50 microgram vaginal misoprostol tablets may be a reasonable treatment of choice where a quicker delivery needs to be achieved and facilities for intensive monitoring are available. Mechanism of action of transcervical balloon catheters placement of a cervical balloon catheter (such as a Foley's catheter) is thought to cause cervical ripening by the physical, mechanical stretching of the cervix, which in turn stimulates release of endogenous PGs. A recent study using immunoassay and immunohistochemistry showed that, when used for preinduction cervical ripening, Foley catheters affect cervical ripening through changes in biochemical mediators. Levels of interleukins (IL-6, IL-8), matrix metalloproteinase (MMP)-8, nitric oxide synthetase (NOS) and hyaluronic acid synthetase (HAS-1) were significantly higher in women who have received a Foley's catheter [11].

The FDA approved the Cook cervical ripening balloon in 2013. This is an 18 French silicone double balloon catheter (balloon capacity 80 ml each), which comes with an optional stylet to aid insertion [12]. Single balloon Foley's catheter versus double balloon Catheter. Recent evidence show no significant difference in delivery intervals or modes of birth between use of the single balloon Foley's catheter over the double balloon catheter. The Foley's catheter is not currently licensed for pre-induction cervical ripening unlike the double balloon catheters [13]. A 2014 systematic review and meta-analysis compared the use of low volume (30 ml) and high volume (60 ml, 80 ml) Foley's bulbs. High volume Foley's catheters resulted in a significantly reduced likelihood of failure to deliver within 24 hours and the reduction was greater with use of 80 ml Foley catheters than with 30 ml Foley's catheters. The rate of caesarean section with use of 80 ml Foley's catheters was not significantly different to that observed with the 30 ml Foley's catheters, but the overall risk ratio slightly favoured the high volume Foley's catheters.

**Current guidelines on methods for IOL:** The current National institute for health and care excellence [NICE] guidance [14] on

IOL states that vaginal PGE2 (as a tablet, gel or controlled-release pessary) should be used as the first-line agent. Misoprostol should be offered as a method of IOL only to women who have intrauterine fetal death, or in the context of a clinical trial. It also suggests that mechanical methods (balloon catheters, Laminaria tents) should not be routinely used for IOL. The Royal College of Obstetrics and Gynecology [RCOG's] guidance on vaginal birth after a caesarean (VBAC) indicates that PGs should be used with caution, as prostaglandin use is associated with an increased risk of uterine rupture. Further research should be done into mechanical methods for IOL in VBAC patients was recommended [15].

World Health Organization recommendations [WHO] [16] include the use of oral (25 microgram, 2-hourly) or vaginal misoprostol (25 microgram, 6-hourly). However, misoprostol is not recommended for use in women who have had a previous caesarean section. WHO also suggests that, in general, other low-dose vaginal PGs (PGE2) and balloon catheters are suitable. If PGs are unavailable, intravenous oxytocin, or a combination of intravenous oxytocin and a balloon catheter, may be used as an alternative method.

Society of Obstetrics and Gynecology of Canada (SOGC) [17] released a clinical practice guideline in 2013. Salient points include: Intracervical Foley's catheters are acceptable agents that are safe both in VBAC and in the outpatient setting. Double lumen catheters may be considered a second line alternative. Neither PGE2 (cervical and vaginal) nor misoprostol should be used in VBAC because of an increased risk of uterine rupture.

## Material and Methods

This is a prospective observational study conducted in the Department of Obstetrics and Gynaecology at District hospital Dharwad. Patients were selected after proper counselling and getting their consent. A total of 200 antenatal women with maternal or fetal indication for induction of labor and unfavourable cervix were taken up for this study. The sample size calculation is shown in the screenshot obtained using Stat Calc calculator provided by EpiInfo by CDC. The population size is 4800 (12 months study duration, approximately 400 deliveries per month. Hence,  $12 \times 400 = 4800$ , number of deliveries during the study duration). The expected frequency of the disease is the prevalence of induction of labour, which is estimated to be around 13%. Based on FIGO online textbook [ref number] Ramoz LS, Kaunitz AM. Induction of Labour. Available from: [https://www.glowm.com/section\\_view/heading/induction-of-labor/item/130](https://www.glowm.com/section_view/heading/induction-of-labor/item/130). At 95% confidence level, the sample size comes to be 198.

## Statistical Analysis

Data was entered in MS excel spreadsheet and analysed using Microsoft Excel 365 v 2020. Qualitative data: Proportions were used to describe qualitative data. Chi-square test will be used to test the difference between two proportions.

**Quantitative data:** Mean and SD will be used to describe quantitative data, t test was used to test the difference between means.

**Comparison between groups:** 2x2 tables were constructed and proportions were compared using Chi-square test. Fishers' exact test was used for small numbers. Statistical significance was expressed as p value, with a value of <0.05 taken as significant. Comparison between quantitative numerical data:

Tests of normality was applied and Mann-Whitney U test / students't test was applied as was appropriate. Statistical significance was expressed as p value, with a value of <0.05 taken as significant.

#### Inclusion Criteria

1. Singleton pregnancy
2. Cephalic presentation
3. >40 weeks of gestation with indication for induction.

#### Exclusion criteria

1. One or more previous LSCS
2. Teenage pregnancy.
3. Previous Uterine surgery like myomectomy.
4. Estimated fetal weight >4kg
5. Contracted pelvis
6. PROM
7. Medical or obstetrical complication (Placenta previa, twin gestation, Polyhydramionos).

#### Methodology

Every woman included in this study was counselled 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 Tomogram (CTG) evaluation was done and only those with reactive and reassuring CTG were included.

#### Procedure

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 of 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 falls out or after removal at 24 hrs to assess the Bishop's Score. When the cervix has become favourable [ie, Bishop Score  $\geq 6$ ] induction [ARM, Pitocin or ARM + Pitocin] started. Once pregnant women enter active phase of labour will be monitored with partograph. If cervix is unfavourable <6 other ripening methods are 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, 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.

#### Observations and Results

This was a study conducted on 200 patients. The gravidity distribution of the patients is shown in figure number.

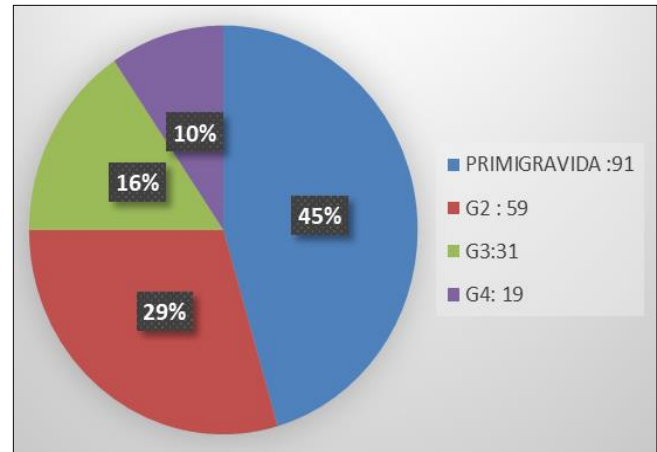


Fig 4: Gravidity distribution.

As shown in figure number, majority of the patients were primigravidae (91%). There were 29% (59/200) second gravidae and 16% third gravidae. Small proportions (10%) were fourth gravida or more. Out of the 200 patients, 15 patients had one prior abortion and 4 patients had two prior abortions.

Table 4: Gestational age distribution.

Gestational age (weeks)	Number	Percentage
40-40.6	172	86%
41.0-41.6	25	12.5%
42	3	1.5%

Out of the 200 patients, majority 86% had a gestational age of less than 41 weeks. The remaining had a gestational age of more than 41 weeks, of which only 3 patients had a gestational age of 42 weeks or beyond.

#### Occurrence of spontaneous expulsion

Spontaneous expulsion occurred in 92 (46%) and did not occur in 108 (54%).

#### Duration of time taken for spontaneous expulsion

In those where spontaneous expulsion did not occur, the catheter was removed at 24 hours.

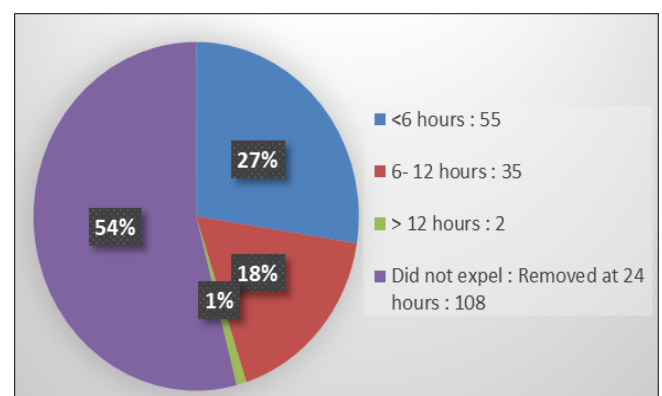


Fig 5: Induction-expulsion duration.

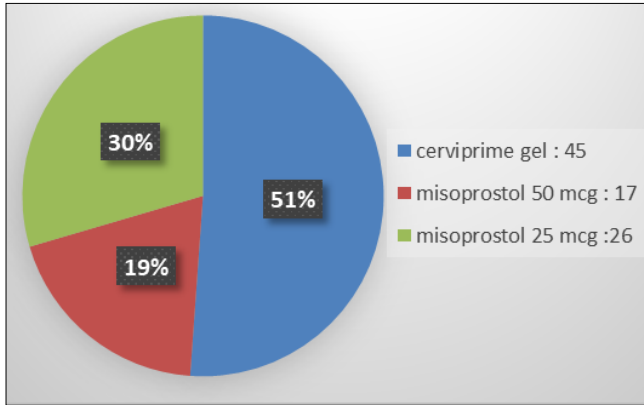
As shown in figure number, 108 patients (out of 200) did not expel the catheter for 24-hour duration. Among those who did expel the catheter, 27% expelled it within 6 hours of expulsion, 18% did so between 6 hours and 12 hours of insertion. Only 2 patients expelled it between 12 hours and 24 hours of insertion.

**Table 5:** Time taken for spontaneous expulsion of catheter (n = 92)

Mean	6.41 hours
Standard Deviation	1.87 hours
Minimum	3 hours
Maximum	14 hours

**Need for additional method of induction of labour:**

Of the 200 patients, 112 patients did not need an additional method of induction of labour. Of the 88 patients who needed an additional method of induction of labour, the mode used is presented in figure number.

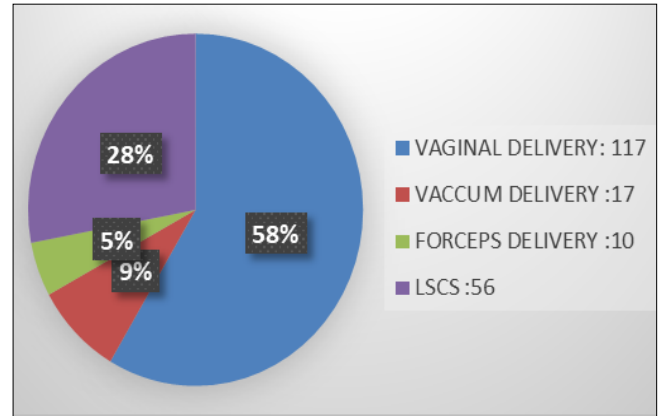


**Fig 6:** Additional methods of induction used

As can be seen in the figure, among those who followed by misoprostol 25 mcg and the least used was misoprostol 50 mcg.

needed an additional method of induction, the most common agent used was cerviprime. This was

**Need for oxytocin augmentation:** Out of the 200 patients in the study, the number of patients who needed augmentation were 109. The remaining did not require oxytocin.

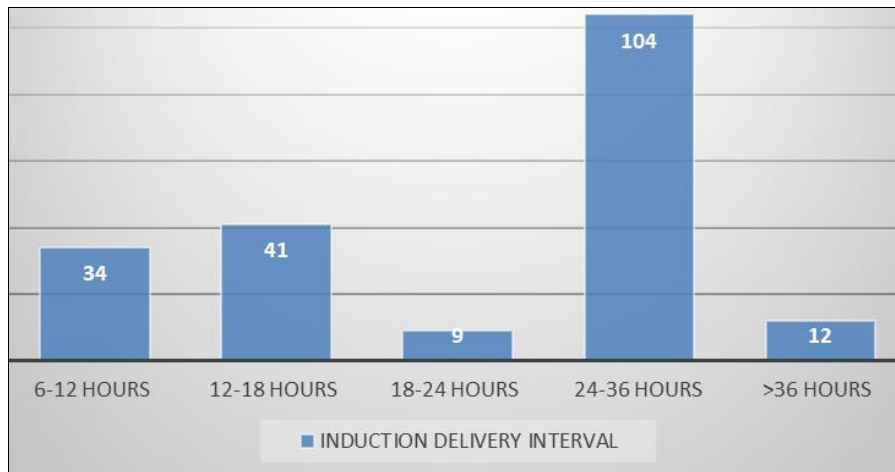


**Fig 7:** Mode of delivery.

Shows the distribution of the modes of delivery. 117 patients (58%) had a normal vaginal delivery. This was followed by 56 patients (28%) who had a caesarean section. The proportion of patients who delivered by instrumental vaginal delivery was much less.

**Table 7:** Showing indication of LSCS

Sr. no	Indication of LSCS	Percentage
1	Failed induction	18 (32.14%)
2	Msaf	12 (21.42%)
3	NRFHR	16 (28.57%)
4	Protracted active labor	4 (7.14%)
5	Obstructed labor	3 (5.35%)
6	Others	3 (5.35%)



**Fig 8:** Induction delivery interval

Majority of the patients (104/ 200 patients) had duration between 24 and 36 hours. A lesser proportion (41/200 patients) had a duration between 12 and 18 hours and between 6 and 12 hours (34/200 patients). The least proportion of patients were those who delivered between 18-24 hours and more than 36 hours.

**Table 7:** Neonatal Birth weight

	Number	Percentage
<2500 grams	11	5.5%
2500-3500 grams	133	66.5%
>3500 grams	56	28%



The neonatal birth weight distribution is shown in table number. There were 107 males and 93 females.

**Table 8:** Neonatal outcomes

	1 <sup>st</sup> minute	5 <sup>th</sup> minute
Number of neonates with Apgar score 6/10 or less	39	35
Number of neonates with Apgar score 7/10 or more	161	165

As shown in table number, the proportion of neonates who had a 5 minute apgar score of less than 6/10 was 17.5%. 36 neonates required NICU admission and all the neonates were discharged within 48 hours. Of this, 21 were discharged within 24 hours of admission. However, only one neonate had poor neurological outcome. So, overall, there was excellent neonatal outcome in

**Table 10:** Comparison of duration taken for expulsion (among those who expelled spontaneously only)

Induction expulsion interval	Primigravidae (n=40)	Multigravidae (n=52)	Unpaired t test, p value 0.0317 Statistically significant difference
Mean	6.825	6.096	
Variance	5.01	2.16	

The induction-expulsion interval was 6.82 +/- 5.01 hours in the primigravidae and 6.096 +/- 2.16 hours in multigravidae. Upon comparing with unpaired t test, the difference is statistically

this set of patients.

**Table 9:** Comparison of rate of expulsion between primigravidae and multigravidae.

	Expulsion occurred	Expulsion did not occur
Primigravidae	40	51
Multigravida	52	47
p value 0.2488, Chi-square test, Not statistically significant		

As shown in table number, expulsion occurred in 43.95% (40/91) primigravidae and in 47.7% (52/109) multigravidae. Upon comparing with chi-square test, there was no statistically significant difference. This implies that the success of the EASI catheter was similar in primigravidae and multigravidae.

**Table 11:** Comparison of induction delivery interval between primigravidae and multigravidae

Induction delivery interval	Primigravida (n=40)	Multigravida (n=52)	t Stat 3.92 Unpaired t test, p value <0.001 Highly statistically significant
Mean	18.35	13.03	
Variance	66.13	22.50	

The duration of induction-delivery was 18.35 hours in primigravidae and 13.03 hours in multigravidae. Upon comparing this with the unpaired t test, the difference is highly

significant. This implies that multigravidae are likely to take much lesser time than primigravidae to expel the EASI catheter.

statistically significant. This implies that among use of EASI catheter reduces the induction delivery interval in multigravidae, as compared to primigravidae.

**Table 12:** Comparison of modes of delivery

	Vaginal	Vacuum	Forceps	LSCS
Expulsion Occurred	53	9	6	24
Expulsion Did Not Occur	64	8	4	32
P value 0.6368; Fischers exact test; Statistically not significant				

As shown in table number, the proportion of patients who underwent LSCS in the group where expulsion occurred (24/92) was similar to that of the group where expulsion did not occur (32/108). Upon comparing with Fischer's exact, test there was no statistically significant difference between the groups. This

implies that success or failure of expulsion of the EASI catheter does not influence mode of delivery. In other terms, use of EASI catheter does not result in increased LSCS rate or operative vaginal delivery.

**Table 13:** Need for additional method of induction in relation to spontaneous expulsion

	Induction Needed	Not Needed
Expulsion Occurred	45	47
Expulsion Did Not Occur	41	67
P VALUE 0.1154; Chi-square test, no statistically significant difference		

The proportion of patients in the group where expulsion occurred and needed additional method of induction was 45/92 (%). The comparable proportion in the group where expulsion did not occur was 41/108 (%). Upon comparing with chi-square

test, the difference was not statistically significant. This implies that immaterial of whether EASI catheter gets expelled on its own or no, some additional method of induction may be required.

**Table 14:** Need for oxytocin augmentation in relation to spontaneous expulsion

	Needed oxytocin augmentation	Did not need oxytocin augmentation
Spontaneous expulsion of EASI	46	46
No spontaneous expulsion of EASI	63	45
P value 0.2568, Chi-square test. No statistically significant difference		

The proportion of patients in the group where expulsion occurred and needed oxytocin augmentation was 46/92 (50%). The comparable proportion in the group where expulsion did not occur was 63/108 (%). Upon comparing with chi-square test, the

difference was not statistically significant. This implies that immaterial of whether EASI catheter gets expelled on its own or no, there is additional need for oxytocin augmentation.

**Table 15:** NICU admission rate in relation to EASI expulsion rate

	NICU admission	No NICU admission
Expulsion occurred	19	73
Expulsion did not occur	17	91
p value 0.4606	Not statistically significant	

The NICU admission rate among those who had expulsion of EASI was 19/ 92 (%). The corresponding proportion among those who did not have expulsion of EASI was 17/108 (%).

Upon comparing using the chi-square test, there is no statistically significant difference

**Table 16:** Comparison of outcomes between gestational (less than 41 weeks and more than 41 weeks)

	Gestational age <41 weeks	Gestational age >41 weeks	
<b>Occurrence of spontaneous expulsion</b>			
Occurred	79	13	P value 1.0
Not occurred	93	15	
Insertion expulsion interval	15.84	15.60	P value 0.896
<b>Need for additional induction method</b>			
Needed	97	15	P value 0.838
Not needed	75	13	
<b>NICU admission</b>			
NICU admission not needed	143	21	P value 0.297
NICU admission needed	29	7	

There was no difference in the occurrence of spontaneous expulsion, insertion expulsion interval, need for additional induction method or NICU admission rate, between those who were less than 41 weeks or more than 41 weeks.

## Discussions

**Comparison of induction delivery interval between primi and multigravida:** In present study the duration of induction-delivery was 18.35 hours in primigravidae and 13.03 hours in multigravidae. Upon comparing this with the unpaired t test, the difference is highly statistically significant. This implies that among use of EASI catheter reduces the induction delivery interval in multi gravidae, as compared to primigravidae.

**Comparison of modes of delivery:** In present study the proportion of patients who underwent LSCS in the group where expulsion occurred (24/92) was similar to that of the group where expulsion did not occur (32/108). Upon comparing with Fischer's exact, test there was no statistically significant difference between the groups. This implies that success or failure of expulsion of the EASI catheter does not influence mode of delivery. In other terms, use of EASI catheter does not result in increased LSCS rate or operative vaginal delivery.

**Need for additional method of induction in relation to spontaneous expulsion:** In present study the proportion of patients in the group where expulsion occurred and needed additional method of induction was 45/92 (%). The comparable proportion in the group where expulsion did not occur was 41/108 (%). Upon comparing with chi-square test, the difference was not statistically significant. This implies that immaterial of whether EASI catheter gets expelled on its own or no, some additional method of induction may be required.

**Need for oxytocin augmentation in relation to spontaneous expulsion:** In present study the proportion of patients in the group where expulsion occurred and needed oxytocin augmentation was 46/92 (50%). The comparable proportion in

the group where expulsion did not occur was 63/108 (%). Upon comparing with chi-square test, the difference was not statistically significant. This implies that immaterial of whether EASI catheter gets expelled on its own or no, there is additional need for oxytocin augmentation.

**NICU admission rate in relation to EASI expulsion rate:** In present study the NICU admission rate among those who had expulsion of EASI was 19/ 92 (%). The corresponding proportion among those who did not have expulsion of EASI was 17/108 (%). Upon comparing using the chi-square test, there is no statistically significant difference

**Comparison of Outcomes Between Gestational Age Less Than 41 Weeks and More Than 41 Weeks:** In present study there was no difference in the occurrence of spontaneous expulsion, insertion expulsion interval, need for additional induction method or NICU admission rate, between those who were less than 41 weeks or more than 41 weeks.

**Reason for LSCS In Present Study:** In present study 56 post-dated antenatal women land up in LSCS in which 18 because of failed induction, 12 cases because of MSAF, 16=NRFH, 4= protracted active labor, 5= obstructed labor and 6 cases because of cord prolapse. Most probable cause of NRFH and MSAF augmentation with agents like oxytocin, prostaglandin and dinopristone gel. No significant maternal or fetal complications observed in this study.

Results of present study shown that induction to delivery interval is less after augmentation of labor with other methods of induction like prostaglandins and oxytocin. 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 deliveries is with Foley's catheter group.

Indications for CS were mainly due to failed induction (32.14%) Fetal distress (28.42%)- which may not be directly due to EASI,

because all these cases are after spontaneous expulsion of EASI or removal after 24 hours.

**Adverse Effects:** 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 and prostaglandins. The main complication reported in previous studies were acute transient febrile reaction, chorioamnionitis, NRFHR, vaginal bleeding etc. No such fetomaternal complications observed in the current study.

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

The majority of studies focused on reducing the duration of labor induction and included primary outcomes related to time to delivery, delivery within 12 to 24 hours, or time to active labor. All potential maternal and fetal complications (e.g., uterine hyperstimulation, uterine rupture, abnormal fetal heart rate, postpartum hemorrhage) and neonatal outcomes (e.g., Apgar's scores, NICU admission) were consistently underpowered. No maternal complications such as cases of fertile illness, chorioamnionitis, vaginal bleeding and no cases of postpartum sepsis noted.

**Postpartum Follow Up:** Patients were followed up in the postpartum period. In the present study no cases of febrile illness, or postpartum endomyometritis were observed. EASI is an effective method for cervical ripening. As compared to other inducing agents like prostaglandins which produce severe painful uterine contractions, hyperstimulation and even uterine rupture it does not produce painful uterine contractions.

EASI resulted in maximum number of vaginal deliveries. Induction to delivery interval is shortened. Numbers of LSCS deliveries are decreased. With EASI, FETO maternal outcome is better with than with other inducing agents. No FETO maternal complications were observed in the present study. EASI is tolerated by women and there were no systemic and serious maternal side effects.

### Conclusion

The success of the EASI catheter was similar in primigravidae and multigravidae. Multigravidas are likely to take much lesser time than primigravidae to expel the EASI catheter. EASI catheter reduces the induction delivery interval in multigravidae, as compared to primigravidae. Implies that success or failure of expulsion of the EASI catheter does not influence mode of delivery. In other terms, use of EASI catheter does not result in increased LSCS rate or operative vaginal delivery. Implies that immaterial of whether EASI catheter gets expelled on its own or no, some additional method of induction may be required. Implies that immaterial of whether EASI catheter gets expelled on its own or no, there is additional need for oxytocin augmentation. There was no difference in the occurrence of spontaneous expulsion, insertion expulsion interval, need for additional induction method or NICU admission rate, between those who were less than 41 weeks or more than 41 weeks.

### Acknowledgement

It is a privilege to express my sincere and deepest gratitude towards my teacher & guide Dr. Satish Shetty, whose invaluable guidance, constant encouragement, timely help, affectionate attitude, healthy criticism and valuable suggestions helped me to

complete my work. I extend my utmost heartfelt regards to all my honourable teachers and Dr. U.S. Hangarga who has inculcated his vast knowledge and experience made my learning not only possible but meaningful.

### Author's Contribution

Not available

### Conflict of Interest

Not available

### Financial Support

Not available

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**How to Cite This Article**

Somkuwar S, Shetty S. A prospective observational study on efficacy and safety of extra amniotic saline infusion with transcervical foley's catheter in induction of labour in post-dated pregnancy. *International Journal of Clinical Obstetrics and Gynaecology.* 2024;8(1):01-08.

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