



COMPARSION OF FOLEYS, FOLEYS WITH EASI (EXTRA AMNIOTIC SALINE INFUSION) FOR INDUCTION OF LABOUR IN WOMEN WITH UNFAVOURABLE CERVIX.

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Abstract :

To compare the efficacy of transcervical foleys catheter alone to transcervical foleys catheter with extra amniotic saline infusion for labour induction and cervical ripening in women with unfavourable cervix. Study type is Observational study. It was conducted in Department of Obstetrics and Gynaecology, PSG Hospitals, Coimbatore. Study subjects were women presenting for labour induction with a singleton, cephalic, intact membranes and unfavourable cervix with adequate pelvis bishops score less than or equal to 5. Eligible women were randomly selected and assigned to receive either Foleys catheter alone or Foleys with Extra Amniotic Saline Infusion(EASI). The primary study outcome was induction to delivery interval, secondary outcome includes maternal and fetal outcome. Fifty women met eligibility criteria and were randomly assigned(Foleys n-25 Foleys with EASI n-25). Study

subjects were of similar parity, gestational age and bishops score. The median induction to delivery interval for foleys alone and Foleys with EASI was found to be similar (16-20 hours p-0.107). Also it was noted that there was no statistical difference between the two groups with regard to mode of delivery. In women with unfavourable cervix, there was no significant difference in efficacy of labour induction of Foleys alone group and Foleys with EASI group.

Keyword :Foleys catheter, Extra Amniotic Saline Infusion, Induction of Labour, unfavourable cervix COMPARSION OF FOLEYS, FOLEYS WITH EASI (EXTRA AMNIOTIC SALINE INFUSION) FOR INDUCTION OF LABOUR IN WOMEN WITH UNFAVOURABLE CERVIX.

INTRODUCTION:

Labour is a process which begins with transformation in the biochemical connective tissue and with gradual effacement

and dilatation of the uterine cervix with the aid of rhythmic uterine contractions of adequate frequency, force and extent. It is known that prolonged labour carries an increased risk of operative deliveries, maternal and fetal morbidities. Induction of labour is an intervention directed towards artificially starting uterine contractions leading to progressive effacement, dilatation of the cervix and delivery of the fetus. Induction of the labour should be simple, safe, effective and preferably non-invasive. The success of induction depends to a large extent on the consistency, compliance and configuration of the cervix. The unripe cervix thus remains a well recognized obstacle to the successful induction of labour. A simple and efficient method of ripening of the cervix before induction is therefore clearly of use. Over the years several methods have been used in the setting of an unfavourable cervix in order to increase cervical favorability and shorten the duration of labour. These include use of pharmacological ripening agents such as prostaglandin analogues and oxytocin as well as mechanical methods, but no single method has been shown to be superior over all other methods. Moreover most of these studies have been conducted in western countries, which may not be applicable our population. Therefore this study was carried out in order to compare the efficacy of two methods of labour induction, namely Foleys with EASI and Foleys without EASI. This study was carried out in those patients with indications for medical induction of labour such as hypertensive disorders in pregnancy, Postmaturity, Gestational diabetes mellitus (GDM), Rh-Isoimmunisation, Intrauterine growth retardation (IUGR), Intrauterine death (IUD), Oligohydramnios and Polyhydramnios. There are various methods by which labour may be induced with definite advantages and disadvantages. Ripening of the cervix may be achieved by mechanical techniques such as introduction of a cervical catheter. Induction by Foleys catheter, Foleys with

EASI (extra amniotic saline infusion) has proven to be safe, effective and quite inexpensive with chances of infection of not more than that of the usual hospital rates if strict aseptic precautions are observed. An inflated Foleys catheter is placed extra amniotically. It causes mechanical trauma to the decidua and fetal membranes which in turn leads to separation of membranes and causes an increase in prostaglandin production in the maternal circulation. This study was undertaken to determine whether the addition of extra amniotic saline infusion improves the efficacy of Foleys catheter in women undergoing cervical ripening and induction of labour with an unfavorable cervix.

OBJECTIVES :

General Objectives: To compare the risks and benefits of induction of labour, by Foleys catheter with or without EASI (extra amniotic saline infusion) in women with unfavorable cervix.

Specific Objectives

To determine induction and delivery interval between the 2 groups.

To detect the maternal and fetal outcome between the women induced Foleys catheter and Foleys with EASI group.

MATERIALS AND METHODS:

This observational Study was conducted between July 2011 to September 2011 in department of Obstetrics and Gynecology PSG Institute of Medical Sciences and Research center Peelamedu, Coimbatore. Fifty women were randomly recruited for this study.

Inclusion criteria:

Women with Singleton pregnancy, cephalic presentation with intact membranes, 36 to 42 weeks of gestation, unfavorable cervix with Bishops score less than or equal to 5 were included in this study.

Exclusion criteria:

Women with previous uterine scar, history suggestive of ante partum hemorrhage, malpresentation, multiple pregnancy and contracted pelvis were excluded.

PREPARATION OF QUESTIONNAIRE/ PROTOCOL

A questionnaire was used to collect information such as age, educational status, occupation, monthly income, chief complaints, history of past illness, family history, menstrual history, contraceptive history and obstetric history.

The study was approved by the Institutional Human Ethics Committee.

Selection of subjects:

The method was explained to the patients and only those who gave consent were finally recruited for the study. Prior to interview, informed consent was taken from every respondent. A total number of 50 patients were randomly selected for this study. The patients were divided into two groups of 25 each. They were, Foley only group – Induction of labour was performed in the traditional way using intra-cervical Foleys catheter. Foley with EASI group – Induction of labour was performed in the same way as in the Foley only group except that after the Foleys catheter was inserted, 300 ml of warm saline was introduced through it in order to induce labour. Other protocols including infusion of oxytocin were followed for both the groups whenever indicated. Soon after admission, each patient was interviewed in

detail followed by a thorough physical examination. The last menstrual period was ascertained and corrected after clinical examination. A Bishop scoring system was used to assess the ripening of the cervix. They were then randomly assigned to either the Foley only group or the Foley with EASI group before they were taken to the labour ward.

Foley only group:

The traditional method of induction of labour was used. A rubber catheter was placed in the extra amniotic space which causes separation of the fetal membranes. The insertion of the catheter stimulates local prostaglandin release which in turn leads to cervical ripening. The catheter that is used is generally made up of rubber as it is an inert substance and does not lead to any systemic complications. A 16 size Foleys catheter was introduced through the cervix using a sterile technique with the aid of the speculum and sponge holding forceps. Forty ml of distilled water was instilled into the balloon. The patient was observed closely. After the patient went into active labour, the condition of the cervix was reassessed and artificial rupture of membranes was done if needed. If despite expulsion of the catheter, the patient did not go into established labour, oxytocin drip was started. In some cases if the catheter remained *in situ even after 24 hours, oxytocin drip was started after a reassessment.*

Foley with EASI group:

As mentioned above, Foleys catheter was introduced into the cervix. Then about 300 ml of warm normal

saline solution was infused through the catheter. This additional step is thought to further facilitate the separation of amniotic membrane. They were reassessed after 24 hours, if Foleys catheter not expelled, oxytocin was infused intravenously if needed. The following data were recorded: maternal age, gestational age, pre-induction and post-induction Bishop's score, presence of gestational hypertension, gestational diabetes, thyroid status, heart disease, oligohydramnios and polyhydromnios

In addition to the above data, the mode of delivery such as vaginal, vacuum-assisted, caesarean section were also recorded Data were analyzed using the Statistical Package for Social Science, version 16.0. The X^2 test was used to compare the significance between the two groups.

RESULTS:

There was no significant difference in the basal characteristic features such as maternal and gestational age between the Foley only group and Foley with EASI groups as shown in table 1.

Table: 1

Characteristic	Foley (n=25)	Foley with EASI (n=25)	P value
Maternal age	23.2 \pm 2.08	23.0 \pm 2.51	0.761
Gestational age	39.6 \pm 1.27	39.42 \pm 1.234	0.631
Pre - induction Bishop's score	2.24 \pm 1.05	2.48 \pm 0.918	0.394
Post - induction Bishop's score	6.48 \pm 1.25	6.72 \pm 1.06	0.490

Values are shown as mean (±SD)

Table : 2 Indications of induction labour between two groups

Indication	Foleys(n=25)		Foleys with EASI (n=25)	
	No	%	No	%

Gestational Hypertension	2	50%	1	7.7%
Hypothyroid	2	50%	1	7.7%
Oligohydramnios	0	0%		
GDM on insulin	0	0%	1	7.7%
Heart disease RHD	0	0%	1	7.7%
Polyhydramnious	0	0%	1	7.7%

Table : 3 shows mode of delivery between the 2 groups

Delivery	Foley (n=25)		Foley with EASI (n=25)		P value
	No	%	No	%	
VD	21	84%	20	80%	0.663
Vacuum	2	8%	2	8%	
LSCS	2	8%	3	12%	
Mean \pm SD	1.24 \pm 0.59		1.32 \pm 0.690		

Duration	Foley (n=25)		Foley with EASI (n=25)		P value
	No	%	No	%	
Less than 16hrs	3	12%	0	0%	0.107
16-20hrs	21	84%	23	92%	
More than 20hrs	1	4%	2	8%	
Mean \pm SD	1.92 \pm 0.40		2.08 \pm 0.27		

DISCUSSION:

In this present study transcervical Foleys catheter alone was compared with transcervical Foleys catheter with extra amniotic saline infusion for cervical ripening and labour induction in women with an unfavorable cervix. Results from this study demonstrate that the addition of extra amniotic saline infusion to Foleys catheter used for labour induction results neither in shorter induction – to – delivery intervals nor of improved delivery outcomes when compared with induction with Foleys alone. It is unclear whether differences in the study population or methodology can explain the difference in findings observed between our study and of Guinn *et al*¹, and the trial by Karjane *et al*⁹, all of which compared the efficacy of Foleys with extra amniotic saline infusion and Foleys alone as an adjuvant to labour induction. Extra amniotic saline infusion was achieved with 300 ml of warm normal saline. In our study a Foleys catheter infused with 40 ml of normal saline and balloon was taped to the inner thigh with minimal tension, compared to the Guinn *et al*¹ where 30 ml of saline was infused and balloon taped

to inner thigh with minimal tension. In contrast, the trial by Karjane *et al*⁹ a 50ml saline was used and balloon was tapped without tension. However, because both the extra amniotic saline infusion and Foleys only group in our study received the bulb and catheter of same size, this should not cause a differential effect between the two groups. Although the efficacy of Foleys alone and Foleys with extra amniotic saline infusion is thought to be largely related to its mechanical effects on the cervix to promote cervical ripening, there is newer data to suggest that Foleys bulb alone acts not only by mechanical dilation but also by cytokine release¹⁰. Extra amniotic saline infusion in theory may also lead to cytokine release through a membrane stripping effect. However, if extra amniotic infusion dilutes and washes out the cytokines released by membrane stripping, then the theoretical advantage of extra amniotic saline infusion may be attenuated. Thus, the significance of these subtle methodological differences related to the observed results of our trial and those reported by Guinn *et al*¹ and Karjane *et al*⁹ is uncertain and remains an area of focus for future research initiatives. Our study showed that there was no statistical difference in the time from the Foleys insertion to Foleys expulsion in extra amniotic saline infusion group and Foleys group. Furthermore our study demonstrated an increased rate of LSCS in Foleys with EASI group, although it was not statistically significant.

CONCLUSION:

Induction to delivery interval is apparently shortened in the group induced with Foleys but with no statistical significance. There was no statistical difference in efficacy between Foleys group and Foleys with EASI group. It is concluded that cervical Foleys catheter and Foleys catheter with EASI allow successful induction of labour in women with unfavourable cervix. It leads to good maternal outcome with low cost effective.

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