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The Efficacy of Transcervical Foleys Catheter with Extra Amniotic Saline Infusion in Cervical Ripening Before Induction of Labour with Vaginal Prostaglandins

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Abstract
Aim: *To evaluate the efficacy of transcervical Foley catheter with extra amniotic saline infusion in cervical ripening before induction of labour with intravaginal prostaglandin E1.*
Methodology: *106 patients with cephalic presentation, singleton pregnancy with intact membranes having modified Bishop's score < /= 2 were selected. They were randomly divided in to two groups of 53 each. In group A Foley catheter with extra amniotic saline infusion was given for cervical ripening before the induction of labour with intravaginal PG E1 and in group B , PG E1 was given intravaginally without using Foley and extra amniotic saline infusion. Induction to delivery interval was calculated from the time when the intravaginal PG E1 is kept.*
Results: *There was significant improvement in modified Bishop score after Foley catheter expulsion in group A. The mean induction to delivery interval was significantly shorter and rate of vaginal delivery within 24 hours was significantly higher when compared to group B. There was no significant difference in mode of delivery, intra partum complications, rate of ARM, oxytocin use or neonatal outcomes.*
Conclusion: *Intra cervical Foley catheter with extra amniotic saline infusion is an effective method for cervical ripening in women with very unfavourable cervices.*
Keywords: *Induction of labour, Foley catheter, Prostaglandin E1, Modified Bishop's score.*

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 purpose of cervical ripening and induction of labour is to achieve vaginal delivery and to avoid operative delivery by Caesarean section[1]. Ripening of cervix is normally a physiologic process that precedes uterine contractions and includes a highly complex biochemical process. Cervical ripening may stimulate uterine activity and uterine contractions result in cervical ripening. The ideal ripening method should be inexpensive, easy, simple, reversible and safe for mother, fetus and newborn. It should cause quick cervical change in a physiologic manner so that labour can ensue in a natural way.

In 1955, Bishop devised a cervical scoring system for multiparous patients with planned elective

induction of labour in which 0 to 3 points are given for each of five factors. Calder modified the Bishop score and it has become the most commonly used pre induction cervical scoring system[2]. For more than 100 years, obstetricians have used various balloon catheters to induce cervical ripening and labour. In the mid nineteenth century, Barnes was one of the first to describe the use of a balloon catheter to ripen the uterine cervix [3]. In recent years, simple Foley catheters have been used for this purpose. Several authors suggest adding traction on the catheter, whereas others infuse through the catheter 1 ml per minute of normal saline extra amniotically to accelerate the ripening process. The cervical ripening mechanism of extra amniotic balloon is probably twofold: 1. Direct pressure and overstretching of the lower uterine segment and cervix. 2. Local secretion of prostaglandins as evidenced by an increase in PG level in the maternal blood.

A balloon catheter for cervical ripening is contra indicated in patients with a low lying placenta. Most authors consider vaginal bleeding, previous Caesarean section, cervicitis and rupture of membranes as relative contra indications for its use. Balloon catheters can theoretically lead to ascending infection, although no study reported any significant infectious complications from this technique in either the mother or the new born. Cervical ripening with extra amniotic balloon catheters possess the advantages of simplicity, low cost, reversibility and lack of severe side effects[3]. The objective of our study was to evaluate the efficacy of transcervical Foley catheter with extra amniotic saline infusion in cervical ripening before the induction of labour with intravaginal prostaglandin E1.

Materials and Methods

This randomized controlled trial was conducted in SAT Hospital, Govt. Medical College, Thiruvananthapuram for a one year period. The randomized controlled trial was registered under the Clinical Trials Registry India, National Institute of Medical Statistics (Indian Council of Medical Research). 106 gravidas with cephalic presentation, singleton pregnancy with intact membranes having modified Bishop's score </= 2 were selected. They were randomly divided in to two groups of 53 each. Intra cervical Foley catheter with extra amniotic saline infusion was given for cervical ripening prior to the induction of labour with intravaginal PG E1 in group A. In group B , PG E1 was given intravaginally without prior ripening with intra cervical Foley catheter and extra amniotic saline infusion. Patients with scarred uterus, and those with hypersensitivity to prostaglandins were excluded from the study. Patients were randomly assigned by a computer generated sealed envelope method to either the intravaginal misoprostol group or the intracervical Foley catheter group. The envelopes were kept in the labour and delivery unit and drawn in consecutive order. In the first group (Group A), 18 G Foley catheter inflation with extra amniotic saline infusion was given for cervical ripening. 30 ml distilled water was used to inflate the bulb. Bulb was pulled to the level of internal os and 200 ml lukewarm saline instilled extra amniotically in 30 minutes. The reassessment was done either after spontaneous expulsion of the catheter or after 24 hours. Then the change in the Bishop's score was assessed. If it was </= 4, induction was done using intravaginal 25 microgram PG E1 for a maximum of 3 doses. In the second group , PG E 1 was placed to the posterior vaginal fornix without ripening using Foley catheter. The reassessment done after 6 – 8 hours and if the Bishop's score was </= 4, PG E1 was repeated for a maximum of 3 doses.

Artificial rupture of membrane (ARM) was done when the modified Bishop's score was more than or equal to 5. If there was inadequate uterine contractions, Pitocin augmentation was given after 4 hours of ARM. Induction to delivery interval was calculated from the time when the first intravaginal PG E1 is kept to the time of delivery. The data was tabulated using Microsoft Excel 2010 and analysed using Statistical Package for Social Sciences (SPSS) version (13.0) software.

The mean and standard deviation were calculated by averaging the individual values for each group. The results were analysed by Chi square test and student 't' test.

Results

Both the study groups were comparable with respect to age. Most of the selected cases were in the age group of 21 – 24 years. 75.5 % (40) were prigravidas in group A as compared to 66 % (35) cases in group B. In group A, the main indications for induction of labour included gestational hypertension, on date induction, fetal growth retardation etc. and in group B, main indications were on date induction , fetal growth retardation, and gestational diabetes mellitus.

There was statistically significant improvement in cervical score after putting Foley balloon catheter with extra amniotic saline instillation in group A (P< 0.001).

Table 1 . Changes in cervical score in group A after expulsion of Foley catheter

		MBS before Foley			total
		0	1	2	
MBS after Foley expulsion	2	5	2	0	7
	3	18	14	2	34
	4	2	9	1	12
Total		25	25	3	53

88.6 % of patients in group A delivered within 24 hours compared to 77.8 % in group B. This difference is statistically significant.

Table 2 : Comparison of rate of vaginal delivery within 24 hours in both groups

Induction Delivery interval	Group A		Group B		Total		X2	df	p
	No.	%	No.	%	No.	%			
< / = 24 hours	31	88.6	25	67.58	56	77.78			
>24 hours	4	11.4	12	32.42	16	22.22			
Total	35	100	37	100	72	100	4.59	1	0.032

The mean induction to delivery interval in group A is 17.45 compared to 19.86 in group B. This difference is statistically significant (p= 0.047).

In group A, 35 patients (66%) delivered vaginally and in group B , 37 patients (69.8%) delivered vaginally. The rate of Caesarean section is comparable in both groups.

Table 3: Mode of delivery

Mode of delivery	Group A N= 53		Group B N = 53		Total N = 106	
	N	%	N	%	N	%
Normal	35	66	37	69.8	72	67.9
Caesarean	18	34	16	30.2	34	32.1

P= 0.677

The requirement of artificial rupture of membrane and oxytocin for augmentation of labour was comparable in both groups.

Table 4: Number of doses of PG E1 in both groups

No. of doses Of PG E1	Group A		Group B		Total	
	No.	%	No.	%	No.	%
1	22	41.5	17	32.1	39	36.8
2	28	52.8	25	47.2	53	50.0
3	3	5.7	11	20.8	14	13.2
Total	53	100.0	53	100.0	106	100.0

P = 0.068

More patients in group B required maximum dose of PG E1 for labour induction compared to catheter group. But the overall use of PG E1 is comparable in both groups.

There was no significant difference in intrapartum complications like maternal pyrexia, meconium stained amniotic fluid or fetal distress in both groups. Hyperstimulation was not noticed in any of the patients in either arm of the study groups. APGAR score at 1 minute and 5 minute were comparable in both groups. Six babies (11.3%) in group A and eight babies (15.1%) in group B required NICU admission. This difference was also not significant (p= 0.540).

Discussion

Mechanical methods to ripen the cervix for labour induction were developed long back. Compared with pharmacological methods, potential advantages of mechanical methods include simplicity, lower costs and reduced side effects.

In the present study there was a statistically significant improvement in Bishop's score after putting intracervical Foley catheter with extra amniotic saline infusion. The mean induction delivery interval for Foley group (group A) was 17.45 hours compared to 19.86 hours in group B (p=0.047). Kandil M etal reported that Foley catheter is superior to 25 microgram vaginal misoprostol regimen when used to induce labour in primigravidae with post term gestation[4]. James C et al reported an induction delivery interval of 8.7 hours for nullipara and 5.5 hours for multipara when they used Foley catheter with extra amniotic saline infusion for cervical ripening prior to induction of labour[5]. Carbone JF et al reported a shorter mean induction delivery time with the combination of Foley bulb and vaginal misoprostol when compared with vaginal misoprostol alone [6]. In the series reported by Chung JH et al, no statistically significant difference was seen in induction to delivery interval among Foley group, misoprostol group and combination therapy [7].

In our series , no statistically significant difference was seen in the rate of vaginal delivery and Caesarean section in both groups. This is comparable to other studies[7,8]. Oxytocin requirement for augmentation of labour was comparable in both groups in our series. Kandil M et al reported that patients in Foley group had less induction to delivery time interval, but more need for oxytocin augmentation. Overall use of PG E1 was comparable in both groups in our series.

There was no significant difference in intrapartum complications like maternal pyrexia , meconium stained amniotic fluid or fetal distress in both the groups. Hyperstimulation was not noticed in any patient in our series. AT Owolabi et al reported increased incidence of tachysystole and hyperstimulation in the misoprostol group than in the catheter group[1]. Neonatal outcome was comparable in both groups in our series. Series by AT Owolabi et al also reported similar neonatal outcome in both groups[1].

Conclusion

There was significant improvement in modified Bishop's score after Foley catheter expulsion in group A .Most of the women in the Foley group delivered within 24 hours and the mean induction to delivery interval was significantly shorter in the Foley group compared to PG E1 group. The rate of vaginal delivery in both groups were comparable. Within the limitations of the present study it can be concluded that intracervical Foley

catheter with extra amniotic saline infusion is an effective method for cervical ripening in women with very unfavourable cervices.

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