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A Randomized Controlled Trial Comparing Transcervical Foley Catheter With and Without Extra Amniotic Saline Infusion for Induction of Labour

Dr. Swapan Das[1] Dr. Anupama Mahli[2], Dr. Prakash Das[2],
Dr. Biswajit Mahapatra[3]

[1]*Assistant Professor, Department of Obstetrics and Gynaecology, Bankura Sammilani Medical College, Bankura, West Bengal, India.*
[2]*PGT , Department of Obstetrics and Gynaecology, Bankura Sammilani Medical College, Bankura, West Bengal, India.*
[3]*RMO cum Clinical Tutor, Department of Obstetrics and Gynaecology, Bankura Sammilani Medical College, Bankura, West Bengal, India.*

Abstract:
Objective: *To compare the efficacy and safety of transcervical foley catheter alone to transcervical foley catheter with extra-amniotic saline infusion for labour induction and cervical ripening in women with an unfavourable cervix.*
Method: *100 pregnant women (study population) were allocated randomly into two groups. First 50 patients were assigned to treatment with transcervical foley catheter with extra-amniotic saline infusion (study group), and next 50 were assigned to transcervical foley catheter alone (control group). All patients were receiving intravenous oxytocin. All women were kept under antibiotic coverage during the whole procedure. Primary study outcome(induction to delivery time) and secondary outcome (mode of delivery, endometritis, chorioamnionitis, apgar scoring etc.) were recorded.*
Results: *100 women were included in this study, 50 in each group. Baseline demographic characteristics including age, parity, pre-induction bishop's score, indication for induction were comparable between both groups. The mean induction delivery interval in study and control group were 10.57 hrs ±3.24 and 12.43 hrs. ± 3.24 respectively. P value was 0.011 which was statistically significant. Post induction bishop's score was 9.82 ± 1.521 in study group and 9.24 ± 1.271 in controlled group, (P = 0.04) which was statistically significant. Maternal complications were very few and similar in both groups. Apgar score in 5 mins was 9.06 ± 0.998 in study group and 8.84 ± 1.167 in control group. 18% of newborn in study group and 26% of newborn in control group admitted in SNCU.*
Conclusion: *Foley catheter with extra-amniotic saline infusion is more efficacious method for induction of labour when compared to induction of labour with foley alone. Both methods are safe as they cause less neonatal and maternal complications and few admission of early neonates in SNCU.*
Keywords: *Induction of labour, Transcervical foley, Extra-amniotic saline infusion.*

I. Introduction

Induction of labour is one of the most common procedure in obstetrics and one of the fastest growing medical procedure in developed countries like United States, where its incidence has increased more than double from 9.5% in 1991 to 22.5% in 2006[1]. According to WHO (Year 2011) in developed countries upto 25% of all deliveries at term involved induction of labour[2]. In developing countries the rates are generally lower (in India approx 10%)[3], but in some settings they can be high as those observed in developed countries.

In the course of normal labour , softening and dilatation of the cervix is the result of a complex bio-chemical reactions which make the cervix hydrophilic resulting in a favourable cervix. In absence of these changes, cervix needs to be ripened by artificial means. Induction of labour is initiation of labour by artificial means prior to its spontaneous onset at viable gestational age, with the aims of achieving vaginal delivery. Induction of labour is used when risks to the mother and or foetus with pregnancy outweighs the risk that involved with the interventions. Now a days elective induction, an induction of labour without a medical or obstetrical indication, appears to be rising even more rapidly than induction of labour as a whole. The success of induction of labour is largely dependent on the state of the cervix whose favourability is assessed using bishop's score[4]. Patients with a bishop's score of 4 or less require cervical ripen before induction of labour[5].

It has been seen in various studies that pharmacological methods like oxytocin, prostaglandins stimulates myometrium and thus causing uterine hyperstimulation and foetal distress[6, 7]. Mechanical methods of

cervical ripening act primarily by dilating and stretching the lower uterine segment and cervix, and are usually not associated with uterine hyper stimulation. Several studies suggested that cervical ripening with an extra-amniotic foley catheter, which is a mechanical method of induction of labour has advantages of simplicity, low cost, reversibility and lack of serious side effects[6,7,8]. Various studies have been done in recent past establishing relationship between induction of labour by various methods and incidence of rising caesarean section as a consequence of their failure.

The purpose of our study is to compare the efficacy and safety of usage of foley catheter with and without extra-amniotic saline infusion for induction of labour and to evaluate the success and failure of induction, at a rural tertiary maternity care unit.

II. Aims And Objectives

Aim: To compare the efficacy and safety of transcervical foley catheter alone to transcervical foley catheter with extra amniotic saline infusion for labour induction and cervical ripening in women with an unfavourable cervix.

Specific objectives of the study :

i) Comparing the progress of labour in foley catheter induction with and without extra amniotic saline infusion groups.
ii) Recording the cervical ripening score in each group, before and after catheterisation.
iii) Comparing induction to delivery intervals in two groups.
iv) Rate of caesarean delivery
v) Neonatal outcomes in terms of apgar score at 1 and 5 minutes.

III. Materials And Methods :

This single blinded randomized control trial was conducted in the department of obstetrics and gynaecology of B.S. medical College Bankura, West Bengal from 1st July 2012 to 30th June 2013. All pregnant women admitted to labour Ward were evaluated for eligibility, which included thorough history, foetal status, thorough examination including pervaginal examination to determine the bishop's score. Women with term and singleton pregnancy, cephalic presentation with intact membrane, adequate pelvis and bishop's score of 6 and less were included in the study. Women with significant vaginal bleeding, cephalo-pelvic disproportion, malpresentation, severe local infection, patients in spontaneous labour and woman with previous caesarean section were excluded from the study. By selecting pregnant mothers fulfilling the inclusion criteria by obstetric history and physical examination and meticulously rejecting mothers coming under exclusion criteria, a study population was made. 100 pregnant women (study population) were allocated randomly into two groups. First fifty patients were assigned to treatment with trans-cervical foley catheter with extra amniotic saline infusion (study group), and next 50 were assigned to transcervical foley catheter alone (control group). Eligible women were explained about the procedure. Written and informed consent were obtained. After randomization, women were placed in dorsal lithotomy position and cervix were prepared with povidone-iodine solution. under direct visualization a No. 16 foley catherter was inserted through the cervical canal extra amniotically. Once the balloon was passed beyond the internal os, it was inflated with 30ml distilled water. The catheter was thenpulled back against the internal os and was taped to the inside of the maternal thigh under minimal tension.

In women assigned to extra amniotic saline infusion (study group), 350ml normal saline in room temperature was infused through the foley catheter over 20mins and knot was put at the distal end to prevent the saline from escaping and then strapped to the medial aspect of the maternal thigh with minimal tension.

All women were receiving intravenous oxytocin, initially with low dose of 1mu/ml @ 15 drops per min. and then with gradually increamented dose as mentioned in 'convenient regime' if pregnant mother did not respond to initial dose, keeping a close monitoring over FHR. Satisfactory response to oxytocin drip was considered when 4 to 5 contraction per 10 mins were achieved without causing hyperstimulation. The foley would have to be removed if there was non-reassuring foetal heart rate mandating membrane rupture, spontaneous rupture of membrane or 12 hrs had elapsed since placement. If the foley cather was found still in place after elapsing 12 hrs, it had to be removed and oxytocin drip was to be continued. Induction of labour was set to be failed when cervix fails to dilate more than 4 cm even after 12 hrs of adequate contraction and membrane rupture.

For prophylaxis against Group B steptococcus causing endometritis or chorioamnionitis, patient were kept under antibiotic coverage during the whole procedure. Relevant data were recorded in the bishop's score card, partograph etc. Primary study outcome (induction to delivery time) and secondary study utcome (mode of delivery endometritis, chorioamenionitis, any other maternal morbidity, apgar scoring etc.) were recorded in the proforma data chart and hence comparison of efficacy and safety of transcervical foley catheter with and without extra amniotic saline infusion for induction were done.

Categorical data were combined to obtain frequencies and percentages, while continuous data were presented as means and standard deviations. Proportional data were compared with the x^2 or Fisher exact test and appropriate, continuous data were analysed by the standard 't-test'. Statistical significance was defined as two tailed 'P' value ≤ 0.05. statistical analysis was performed by IBM SPSS Statistics 20.

Approval of the study protocol and clearance was obtained from the ethical review committee of the institution.

IV. Results

The Table 1 Shows the demographic characteristics of the patients. The mean age of patients in study group is 21.44 years and that in the controlled group is 21.78 yrs with SD of 3.17 and 3.58 respectively. The 'P' value is calculated by 't' Test is 0.616 so it is statistically not significant. Regarding parity between two groups primi gravida mothers highest in numbers in each group (28 in study and 22 in control group). The mean gestational age in study group is 39.3 ± 0.66, whereas in control group it is 39.2 ± 0.80. since 'P' value calculated by 't' test is 0.913 it is statically insignificant. The percentage of tribal population is 14% in study group and 18% in control group. The 'P' is 0.786 which is statistically not significant and hence the racial factor in both groups is similar. In the study group 52% mothers are illiterate and 48% are literate whereas in control group 44% mothers are illiterate and 56% are literate since 'P' value calculated is 0.423 there is no difference between the two groups on the basis of literacy. From the Table 1 it is also seen that most of the patients in both groups are coming from rural areas (78% in study group and 72% in control group). 'P' value is 0.645 so it is statistically not significant.

Table 2 shows the anthropometric data in 2 groups. The mean value of height in study group is 156.06 cm ± 7.63cm. In control group mean height is 157.72 cm ± 7.16cm. comparing these two means 'P' value comes to be 0.265 which is statically insignificant. The mean value of weight in study and control group are 57.98kg ± 8.90 and 55.86kg ± 6.61 respectively. 'P value calculated is 0.180 it is statistically not significant. Mean BMI in study and control groups are 23.81 ± 3.46 and 22.63 ± 2.69 respectively, and the 'P' value is 0.060 it is statistically insignificant. Therefore, p[patients in two groups are statistically similar on the basis of BMI.

Table 3 shows comparison of mean Bishop's Score before induction in two groups. It is found that mean bishop's score before induction in study group is 2.98 ± 1.059 and in control group it is 2.88 ± 1.023 and the 'P' value calculated is 0.632 which is statistically not significant.

Table 4 Shows indication for labour induction in both groups are similar and are PIH, Preclampsia, post dated pregnancy, oligo hydramnio IOGR, diabetes and others. Chi-square test value is 12.347 and 'P' value is 0.90 which is > 0.05 thus statistically insignificant.

Table 5 shows clinical parameters after intervention in two groups. The mean value of bishop's score after induction of labour in study and control group are 9.82 ± 1.521 and 9.24 ± 1.271. and the 'P'value calculated is 0.041 which is statistically significant. It is observed in the study that all of the foley catheter was removed spontaneously before duration of 12 hours and none of them were required to remove manually. The mean value of time interval between foley catheter insertion and removal are 4.49 hrs ± 2.09 and 5.50 hrs ± 2.28 for study and control group respectively. Since 'P' value calculated is 0.029 it is statistically significant. The mean value of induction delivery time interval in study and control group are 10.57 hrs ± 3.24 and 12.43 hrs ± 3.24 respectively, 'P' value is 0.011 which is statistically significant.

Table 6 shows the maternal outcomes in two groups. Regarding mode of delivery it is seen that instrumental and caesarean delivery in control group is more than those in study group. In study group total no. of caesarean section is 8 i.e. 16% of all deliveries and total number of forceps delivery is 6 i.e. 12% of all deliveries. Where as in control group the number is 13 (26%) for caesarean and 9 (18%) for forceps delivery. 'P' value calculated is 0.248 which is statistically not significant. Regarding maternal complications in two groups complication present in 12% cases in study group and in control group complication present in 14% cases. On doing Fisher exact test for mothers in two groups with and without complications 'P value come to be 1.00 which is statistically insignificant. Therefore the two groups are almost similar in terms of maternal complications.

Table 7 shows indication for caesarean section. From this table it is clear that in both groups caesarean section was done mostly because of prolonged labour.

Table 8 shows the neonatal outcomes. It is seen that apgar score in both 1 and 5 mins of birth similar in two groups. Regarding meconium stained liquor more no. of babies delivered in control group was meconium stained as compared to the study group (24% Vs 14%) 'P value calculated is 0.308 which is statistically not significant. Regarding neonatal admission in SNCU, it is seen that almost same number of new born babies were admitted in SNCU immediately after birth in each group and the 'P value calculated through Fisher exact test is 0.47 which is statistically insignificant.

V. Discussion

In our study the mean age of patients in study group was 21.44 ± 3.17 yrs and that in control group was 21.78 ± 3.58 yrs while that in Lin Monique study[10], the mean age was 25.3 ± 5.7 yrs in study group (Foley Catheter + EASI) and 25.0 ± 5.7 yrs in control group (Foley catheter only). In our study 56% of mothers in study group and 44% of mothers in control group were nulliparous (P = 0.41). In the RCT done by Monique[10], 57% of nulliparous women were there in study group and 58% were in control group, with P value of 0.48. This data is almost similar to our data. The mean gestational age in our study was 39.3 ± 0.7 and 39.2 ± 0.8 respectively in study and control group (P = 0.913). whereas in Karjane Study[11] they were 39.6 in EASI and 39 in foley catheter group (P = 0.71), while that in Lin Monique study[10] they were 38.6 ± 2.9 in EASI and 39.0 ± 4.5 in the foley group with P value of 0.43.

Regarding race there was significant no. of tribal population attending anti-natal ward of our hospital, 14% in study and 18% in Control group were tribal. As the P value was 0.786 there was no significant difference in the tribal population in 2 groups.

Regarding literacy the P value was 0.423, so there was no difference between the two groups and on the basis of literacy in our study.

Regarding residence P value was 0.645 for rural and urban population in two groups in our study. So the two groups were similar.

In our study mean heights were 156.06 ± 7.63 cm and 157.72 ± 7.16 cm respectively in study and control group (P = 0.265). Mean weights were 57.98 ± 8.90 kg and 55.86± 6.61 kg respectively in study and control group (P=0.180).

Mean BMI 23.81 ± 3.46 and 22.63 ± 2.69 respectively in study and control group (P = 0.060), but in Monique's study[10] BMI in the study and control group were 35.8 ± 8.6 and 34.2 ± 8.7 respectively with P value of 0.20. BMI $<$ 18.5 are considered under weight, 18.5 – 24.9 are normal, 25- 29.9 are overweight and $\geq$ 30 are obese. From this knowledge it is concluded that most of the patients in our study have normal BMI, whereas those participated in Monique's study[10] were obese.

Pre-induction Bishops score in our study was 2.98 ± 1.059 in study group and 2.88 ± 1.023 in the control group. It was 3 in both the groups in the Karjane Study[11], 3.3 in the foley with EASI and 3.7 in the foley group in the Guinn Study[12] , while it was 3 in the foley with EASI and 2 in the foley group in the Lin Monique Study[10]. Statistically these parameters were similar. Thus the groups were comparable in all the studies.

As already discussed in frequency table, PIH, pre-eclampsia, post dated pregnancy, oligo-hydramnios, IUGR, diabetes and elective induction were the indications for induction of labour. P value calculated by chi-square test is 0.90, therefore statistically there is no difference in the indication in 2 groups. Other study such as RCT by Monique at.el[10], RCT by Zafarghandi et.al[13] had also mentioned the similar indications in their study published in AJOG, November, 2010.

In our study Post induction Bishop's score was 9.82 ± 1.521 IN study group and 9.24± 1.271 in control group (P = 0.041) , which is statically significant. The other studies have not considered this parameter as well.

In our study the mean time for spontaneous removal of catheter was 4.49 ± 2.09 hrs in study group and in control group it was 5.50 ± 2.28 hrs (P=0.029) which is statically significant. In RCT by Zafarghandi et.al[13], the mean interval for removal of foley catheter with EASI was 4.9 hrs which is similar to our study. Monique et.al[10] has found similar result, the mean time of foley expulsion was shorter in the EASI group (4.1± 2.3 hrs), than in foley group (5.3 ± 3.2 Hrs) ; P value = 0.005. In our study the induction delivery time interval was 10.57 ± 3.24 hrs in study group and 12.43 ± 2.24 hrs in control group (P=0.011), which is statistically significant. Karjane et.al study[11] , has similar results as ours. Their study showed the induction delivery time was 16.58 hrs in study group Vs 21.47 hrs in control group, P value < 0.01. But in the study the overall duration of labour was more than that of our study. It may be due to the fact that they have not given oxytocin infusion to all patients.

Our present study shows that in study group, 36 (72%) mothers delivered spontaneously by vaginal route, 6(12%) by forceps delivery, and 8 (16%) by caesarean section. In control group, 28 (56%) delivered spontaneously, 9(18%) by forceps and 13 (26%) by caesarean section. The number of caesarean section in mothers who were induced by foley with EASI may appear less numerically as compared to foley only group, but statistically same in both group (P=0.248). Study conducted by Karjane et.al[11] and Monique et.al[10] gave similar results i.e. addition of EASI to foley catheter does not affect the caesarean rate.

In our study maternal complication were very few and similar in both group (6 in study and 7 in control group). Other study conducted by Guinn et.al. and Karjane et.al[11] also showed that there was no difference in maternal complications.

In our study prolonged labour was the main indication for the caesarean section (control – 7, study – 5). Foetal distress for which caesarean section were done is equal in number in both group.

In our study Apgar score in 1 and 5 min were similar in both group. Mean Apgar score in 1 min was 6.98 ± 1.86 in study group and 6.96± 2.128 in control group, (P=0.96) and mean Apgar score in 5 min was 9.06

± 0.998 in study group and 8.84 ± 1.167 in control group (P= 0.314). 14% in study group and 24% in control group were meconium stained in our study (P=0.308) which was statically insignificant.

In our study neonatal admission in SNCU, it was found that 18% of new born in study group and 26% of new born in control group were admitted in SNCU, (P = 0.47).

So in our study it was detected that both the methods of induction of labour were similar in term of neonatal outcomes. In previous studies conducted by Monique et.al[10], Karjane et.al[11] and Guinn et.al[12] similar results were found in neonatal outcomes.

In conclusion induction of labour by using foley catheter with extra amniotic saline infusion results in shorter induction delivery time interval, than foley alone. Thus, foley catheter with extra amniotic saline infusion is more efficacious method for induction of labour when compared to induction of labour with foley alone. Both methods are safe as they cause less foetal and maternal complications and few admission of early neonates in SNCU ; also both of them are cost effective. So both methods are suitable, effective and safe for induction of labour and can be practiced in rural based hospitals and low economic health set ups.

Table - 1 : Demographic Characteristics of Patients

Parameter	**Study group n=50**	**Control Group n=50**	**'p' value**
Mean age in yrs. (SD)	21.44 (±3.170)	21.78 (± 3.582)	0.616
Mean gestational age in weeks (SD)	39.3 (0.66)	39.21(0.80)	0.913
Parity Primi gravid (%) Multigravida (%)	 28 (56%) 22 (44%)	 22 (44%) 28 (56%)	0.409
Race Nontribal (%) Tribal (%)	 43 (86%) 7 (14%)	 41(82%) 9 (18%)	0.786
Literacy Literate (%) Illiterate (%)	 24 (48%) 26 (52%)	 28 (56%) 22 (44%)	0.423
Residence Rural (%) Urban (%)	 39 (78%) 11 (22%)	 36 (72%) 14(28%)	0.645

Table – 2 Anthropometric Data (Height, Weight and BMI)

Parameter	**Study group n=50**	**Control Group n=50**	**'p' value**
Height in cm Mean ± SD	156.06 ± 7.63	157.72 ± 7.16	0.265
Weight in kg Mean ± SD	57.98 ± 8.90	55.86 ± 6.61	0.180
BMI Mean ± SD	23.81 ± 3.46	22.63 ± 2.69	0.060

Table – 3 : Comparison of Mean Bishop's Score before induction in two groups

Group	**Mean ± SD**	**'p' value**
Study n = 50	2.98 ± 1.059	0.632
Control n = 50	2.88 ± 1.023	

Table – 4 : Indication for induction of labour

Indication	**Study n = 50**	**Control n = 50**
PIH	12 (24%)	8 (16%)
Preeclampsia	5 (10%)	6(12%)
Post dated	9 (18%)	13 (26%)
Oligohydramnios	8 (16%)	10(20%)
IUGR	4 (8%)	2 (4%)
Diabetes	0 (0%)	1 (2%)
Elective	8 (16%)	9 (18%)
Others	4(8%)	1 (2%)

Table – 5 : Clinical parameters after interventions

Parameters	**Study n = 50**	**Control n = 50**	**'p' value**
Bishop's score after induction Mean ± SD	9.82 ± 1.521	9.24 ± 1.271	0.041
Interval between foley catheter insertion and removal (hrs) Mean ± SD	4.49 ± 2.09	5.50 ± 2.28	0.029
Induction delivery interval (hrs) Mean ± SD	10.57 ± 3.24	12.43 ± 3.24	0.011

Table – 6 : Maternal Outcomes

Outcomes	Study n = 50	Control n = 50	'p' value
Mode of delivery in number (%)			
CS	8 (16%)	13 (26%)	
Forceps	6 (12%)	9 (18%)	0.248
Spontaneous VD	36 (72%)	28 (56%)	
Complication in number (%)			
No complication			
Complication	44 (88%)	43 (86%)	1.00
	6 (12%)	7 (14%)	

Table – 7 : Indication for caesarean section

Group	Prolonged labour	Foetal distress	Others	Total
Study	5	3	0	8
Control	7	3	3	13

Table – 8 : Neonatal Outcomes

Outcome	Study n = 50	Control n = 50	P value
Apgar score in 1 min Mean ± SD	6.98 ± 1.857	6.96 ± 2.128	0.96
Apgar score in 5 mins Mean ± SD	9.06 ± 0.998	8.84 ± 1.167	0.314
Meconium stained liquor no. (%)	7 (14%)	12 (24%)	0.308
SNCU Admission No. (%)	9 (18%)	13 (26%)	0.47

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