

## **To Compare the Mean Interval from Induction to Delivery, for Trans-Cervical Foley's Catheter with or without Extra-Amniotic Saline Infusion, for Induction of Labour at Term Pregnancy**

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### **ABSTRACT**

**OBJECTIVE:** To compare the mean induction to delivery interval of trans-cervical foley's catheter with or without extra-amniotic saline infusion for induction of labour at term.

**METHODOLOGY:** This randomized controlled study was conducted in Labour room, Arif Memorial Teaching Hospital Lahore for 6 months. 100 patients with cephalic presentation, singleton pregnancy, intact membranes having Bishop's score <6 at gestational age 37-41 weeks were selected. The patients were divided into two groups of 50 each using random number table. The patients induced with foley's catheter alone were labeled as group A while those given extra amniotic saline through foley's catheter were labeled as group B. Patients were augmented with oxytocin in active phase of labour and induction to delivery interval was recorded.

**RESULTS:** The mean age of patients in group-A was 26 years and that in group-B was 26.1 years with standard deviation of 6.3 and 5.5, respectively. The calculated p value was 0.863 which is not significant, so the age factor is similar in both groups. Both groups were also similar on the basis of parity, gestational age and pre-induction Bishop's score as the recorded p value for these was >0.05 so statistically insignificant. Comparison of mean time interval from induction to delivery shows 20.53±6.21 hours in group-A while 15.98±5.43 hours in group-B with p value <0.05 while there was no significant difference in mode of delivery in both groups.

**CONCLUSION:** Our conclusion is that induction of labour by using foley's catheter with extra amniotic saline infusion results in shorter induction to delivery interval than foley's catheter alone, so it is suitable, cost effective, and safe method for induction of labour.

**KEY WORDS:** Induction of Labour, foley's catheter alone to trans-cervical foley's catheter with extra-amniotic saline infusion, extra amniotic saline infusion.

### **INTRODUCTION**

Induction of labour is defined as the artificial initiation of labour before its spontaneous onset.[1] Induction of labour is a very common procedure done in obstetrical setting to enhance the normal vaginal delivery rate, occurring in up-to 30% of pregnancies.[2,3] It is indicated when the advantage of terminating pregnancy outweigh the advantages of its continuation.[4] In the developed world, induction of labour has significantly reduced maternal and perinatal mortality and morbidity.[5] That is why there is an increase in the rate of induction of labour from 9.5% in 1990 to 25.7% in 2017.[6] The success rate and safety of labour induction depends on the state of cervix before induction [7] because women with an unfavorable cervix are at increased risk of prolonged labour with about 25% higher risk of caesarean delivery.[8]

Indications for induction of labour include hypertensive disorders of pregnancy, pregestational and gestational diabetes, chronic pulmonary and renal diseases, chorioamnionitis, intrauterine growth restriction, postdates pregnancy, isoimmunization, and fetal anomalies.[9] The aim of induction of labour is to achieve vaginal birth by stimulating uterine contractions by using several pharmacological and mechanical agents.[10] Common methods for induction of labour are trans-cervical foley's catheter with or without extra amniotic saline infusion, cervical stretching and amniotomy whereas pharmacological methods include oxytocin, and prostaglandins and anti-progestin like mifepristone.[11] The American Congress of Obstetricians and Gynecologists describe the foley's catheter as an acceptable induction agent because of its high efficacy and safety with advantages of low cost, stability at room temperature and reduced risk of tachysystole as compared to pharmacological agents.[12]

The trans-cervical foley's induce labour not only through direct mechanical dilation of cervix but also by stimulating endogenous release of prostaglandins.[13] The stimulatory effect of foley's catheter may be improved by adding the normal saline at 50 ml/hour into extra-amniotic space through stripping of membrane and applying the extra mechanical force.[2]

Advantages of extra amniotic saline infusion (EASI) include low cost, reversibility and lack of systemic side effects. We conducted this study to promote a cost-effective method of induction as currently we are using prostaglandins for induction of labour which is expensive and requires cold chain maintenance. As we have observed and literature also supports the efficacy of EASI so we want to scientifically study it. This may help establish practice guidelines in our own settings.

### **OBJECTIVE OF THE STUDY**

To compare the mean induction to delivery interval of trans-cervical foley's catheter with or without extra-amniotic saline infusion for induction of labour at term.

### **MATERIAL AND METHODS**

This randomized controlled study was conducted in the Labour room, Arif Memorial Teaching Hospital Lahore for 6 months (from August 2020 to January 2021). Sample size of 100 cases (50 in each group) was estimated by keeping confidence level at 95%, power of study at 80% and mean time from induction to vaginal delivery from previous study i.e.  $16.58 \pm 7$  hours with trans-cervical foley's catheter with extra-amniotic saline infusion and  $21.4 \pm 9.9$  hours with trans-cervical foley's catheter alone. The patients were included by using non-probability consecutive sampling technique. Pregnant females of age 20-30 years, presenting at gestational age 37-41 weeks assessed by dating scan with Bishop's score  $\geq 6$  were included in the study while females with non-cephalic presentation, multiple pregnancy, ruptured membranes, or previous uterine scar were excluded from the study. Written consent was taken from all the females after informing about both methods of induction of labour. The demographic data including age, parity, and gestational age were recorded. The patients were divided in two groups using random number table. The patients induced with foley's catheter alone were labeled as group A while those given extra amniotic saline through foley's catheter were labeled as group B. Intra cervical foley's catheter inserted and normal saline infused at the rate of 50 ml/hour in group B patients. Patients were then augmented in active phase of labour (i.e. cervical dilatation  $\geq 4$ cm) with oxytocin and induction to delivery interval recorded. Patients who went beyond 24 hours, were excluded from the study and were managed according to hospital protocol. All the data was gathered in proforma.

Data analysis was computer based. The collected information was entered in software, SPSS version 22 and analyzed through it. Variables like age, gestational age, parity and induction to delivery interval were presented as mean and standard deviation. Mode of delivery was presented as frequency. t-test was used to compare the induction to delivery interval in both groups. p-value  $\leq 0.05$  was considered as significant.

## RESULTS

The mean age of patients in group-A was 26 years and that in group-B was 26.1 years with standard deviation of 6.3 and 5.5 respectively. The calculated p value was 0.863 which is not significant, so the age factor is similar in both groups. Both groups were similar on the basis of parity as the p value was recorded as 0.89 which  $>0.05$  so statistically insignificant. The mean gestational age in group A was 39.3 +0.66 weeks and in group B was 39.2 +0.80 weeks with p value 0.913. Comparison of two means of Bishop's score before induction of labour was done and the calculated P value was 0.45 which is statistically insignificant, so there was no difference in bishop's score before induction in two groups as shown in Table No.1.

Comparison of mean induction to delivery interval was done in Table No. 2, where in group-A mean induction to delivery interval of 20.53+6.21 hours was recorded while in group-B it was 15.98+5.43 hours and p value was recorded as 0.035 which is  $<0.05$ . So there is significant difference between induction to delivery interval in both groups.

Table no. 3 shows that instrumental and caesarean delivery in foley's catheter alone group is more than in foley's catheter with extra amniotic saline group but statistically it is same in both groups as p value is 0.24.

**TABLE No. 1: Baseline Characteristics of females in two groups (n=100)**

Characteristics	Group A (n=50)	Group B (n=50)	P value
Age in years (mean +SD)	26 +6.3	26.1 +5.5	0.863
Parity (mean + SD)	2.95 +2.61	3.02 +2.67	0.89
Gestational age (mean + SD)	39.3 +0.66	39.2 + 0.80	0.913
Pre induction bishop score (mean +SD)	2.4 +1.3	2.3 + 1.4	0.45

**TABLE No. 2: Comparison of mean induction to delivery interval (n=100)**

	Group-A	Group-B	P value
Induction to delivery interval in hours (mean +SD)	20.53+6.21	15.98+5.43	0.035

**TABLE No. 3: Comparison of mode of delivery**

Mode of delivery	Group A	Group B	P value
Caesarean section	13 (26%)	8(16%)	0.248
Instrumental delivery	9(18%)	6 (12%)	
Spontaneous vaginal delivery	28 (56%)	36(72%)	

## DISCUSSION

Induction of labour is a great challenge in today's maternity practice and often done in the interest of mother and fetus. Several studies done in different countries showed that ripening of cervix is successful in 52-82% with use of intracervical foley's catheter.[14] A variety of methods and agents for induction of labor are available but the use of foley's catheter is associated with reduced induction to delivery interval, decreased caesarean section rate and increased rate of spontaneous vaginal delivery.[15]

In the current study, we used trans-cervical foley's catheter alone in comparison to trans-cervical foley's catheter with extra-amniotic saline infusion keeping in mind the advantages of low cost, reversibility and lack of systemic side effects. The idea behind this study was to promote a cost effective method of induction as currently, in our setup we are using prostaglandins for induction of labour which are expensive and require cold chain maintenance. In the literature, though the efficacy of EASI is observed but it required to be proven scientifically in our setup.

Rashid R and colleagues [16] conducted a study in Srinagar regarding comparison of catheter induction versus catheter induction with extra amniotic saline infusion for labour induction and recorded mean induction to delivery interval of 18.29 +7.85 hours in foley's alone group and 14.89 +7.35 hours in foley's plus extra amniotic saline group. The results showed that the number of instrumental and caesarean deliveries were less in foley's with extra amniotic saline group as compared to foley's alone group. These findings are in consistent with our results.

Ameena B et al., [17] conducted a study and compared the effectiveness of hydrostatic membrane sweeping versus cervical foley's balloon for induction of labour and recorded that mean duration from induction to delivery was 29 hours  $\pm$  3.41 in cervical foley's alone while 24hours  $\pm$ 2.69 with hydrostatic membrane sweeping with a difference of about 5 hours, which is similar with the findings recorded in our study. The mean pre-induction Bishop's score in study conducted by Ameena B, et al. was 2.3 +6.3 in foley's alone group and 2.7 +6.7 in other group, comparable with our study. Regarding the efficacy of catheter balloon, Lee HH et al., [18] conducted a meta-analysis on eight randomized trials showed that labour induction using intracervical foley's catheter shortens induction to delivery time which is in agreement with the results of our study.

On the other hand, Mei dann et al. study [19] compared foley's catheter to cook's catheter showed that cook catheter is costly and showed no significant difference in time from insertion to removal but cervical foley's and extra amniotic saline infusion (EASI) group showed significantly shorter insertion to delivery time. Another multivariate analysis showed that EASI is an independent predictor of shorter induction to delivery interval. [20] Other studies revealed that foley's catheter with oxytocin and EASI have increased rate of vaginal delivery and lower rate of tachyarrhythmias. [21,22]

Regarding comparison of foley's catheter alone and foley's catheter with extra amniotic saline infusion Karjane et al. conducted a study and found time from induction to delivery as 16.5 +7 hours in extra amniotic saline infusion group compared with 21.4 +9.9 hours in foley's alone group almost similar to our results. [23]

In the light of results of our study, supported with other studies, it is established that induction with foley's catheter along with extra amniotic saline is more efficacious than foley's catheter alone and shortens induction to delivery interval. The limitation of our study was that we did not compare any complications between two groups for which some other studies are required to be conducted.

## **CONCLUSION**

The induction with foley's catheter along with extra amniotic saline results in shorter induction to delivery interval as compared to foley's catheter alone with similar rate of caesarean deliveries in both groups, so this method of induction of labour must be referred over foley's alone.

## **CONFLICT OF INTEREST**

There is no conflict of interest shown by any author

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