

Successful Induction of Labour: A Step to Reduce the Alarming Cesarean Section Rates

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ABSTRACT

Background: To reduce the caesarian section rates, induction of labour (IOL) & vaginal births must be encouraged by health care providers. For the induction of labor, cervical ripening by intra cervical foley catheter insertion is an old, effective & safe mechanical method in comparison of prostaglandin (PG) suppositories.

Objectives: To compare the efficacy in terms of mean induction to delivery time between trans-cervical Foley's catheter and intra cervical prostaglandin E2 for induction of labour.

Study design: a randomized controlled trial conducted in the Department of Obstetrics & Gynecology, Civil Hospital, Bahawalpur.

Study duration: July to December 2019.

Materials & Methods: A total of 60 women, aged 18 to 40 years, with cephalic, singleton pregnancy undergoing an induction of labour at a gestational age 37-41 weeks were included. Patients presenting with prelabour rupture of membrane, multiple pregnancy, previous history of caesarean section, HTN and DM were not included in the study. Lottery method was used to place all selected patients in two equal groups i.e. Group A (trans cervical Foley's catheter) & Group B (intracervical prostaglandin E2). The mean induction to delivery time was measured in both the groups.

Results: Mean age of the patients in group A was 30.67 ± 5.09 years while in group B was 31.33 ± 5.58 years. Mean gestational age was 39.12 ± 1.24 weeks. Mean parity was 2.63 ± 1.07 . In my study, induction to delivery time with the use of Foley catheter was significantly lower than that of PGE2 group (p-value = 0.0001).

Conclusion: This study concluded that trans-cervical Foley's catheter can be used effectively for successful induction of labour to reduce abdominal delivery as compared to intra-cervical prostaglandin E2.

Keywords: mechanical method, trans cervical Foley catheter, prostaglandin vaginal pessaries, PGE2, induction to delivery time.

INTRODUCTION

A worldwide rising trend has been observed in the obstetric practice for labour induction. The rate in the Great Britain, ranges from 6-25% with the average being about 20%. In the United States of America this rate is approximately 13% whereas it is 37.5% in Sri Lanka, which is one of the highest in the world¹. IOL aims to deliver a healthy baby while maintaining the health of the mother². Labor induction is an intervention that artificially initiates uterine contractions leading to progressive dilatation and effacement of the cervix and birth of the baby³. IOL is considered when the risks of continuing pregnancy are more than the risks of terminating it.³ Sometimes it is necessary to bring on labor artificially because of safety concerns for the child or mother.⁴ Labor induction is a intervention used for a broad range of common conditions like pre-eclampsia, eclampsia, post-term pregnancy, pregnancy induced hypertension, premature rupture of membranes, chorioamnionitis, IUGR, fetal death, and maternal diabetes.^{5,6}

A successful vaginal delivery is less likely, In the absence of a favorable or ripe cervix. A Bishop's score less than 6 is considered to be an unfavorable cervix. Both chemical and mechanical methods are available for cervical ripening. Prostaglandin (PGE1 and PGE2, PGF2 alpha) preparations as chemical and intra cervical

catheters (single & double balloon) as mechanical method are most widely studied methods.^{7,8} The mechanical methods are among the oldest methods to initiate the process of labor. With advancement in health & medicine sectors, pharmacological methods have widely replaced the mechanical methods.

Prostaglandin E2 suppositories and Foley catheter can be used in ripening of the cervix ,as mechanical methods.⁹ In early 1967 ,Embrey and Mollison elaborated the use of a trans cervical Foley catheter for the cervical ripening.¹⁰ Farah Z & colleagues documented the effectiveness of foley's catheter in rising the Bishop's score in females with Unripe cervix.¹¹ Previous data suggests non-inferiority of single-balloon catheter versus prostaglandins(1 & 2) with regards to ripening of cervix & effectiveness for IOL.¹²

There is alarming rise of caesarian section rate in many countries. The rate of caesarian section has reached to 50 % in our teaching unit, that is much higher than the acceptable rate (10-15%) given by WHO.¹³

This rise is leading into increasing morbidity in terms of placenta previa, placenta accrete, obstetric hysterectomy, postpartum hemorrhage, & eventually increase risk of maternal deaths. It also puts more burden for operation theater facilities & anesthesia coverage especially in poor resources countries. So, in view of this, I

had planned to improve our hospital IOL protocols, & guide our junior doctors to be more ambitious for IOL & vaginal births, along with proper counseling of patients. I conducted this study to compare the efficacy in terms of mean induction to delivery time between trans-cervical folly's catheter and intracervical prostaglandin E2 in local population. This study will help in rebuilding of confidence towards safest & effective method of IOL among trainee doctors, decreasing the abdominal deliveries & associated morbidity & mortality.

MATERIALS & METHODS

This was a Randomized controlled trial conducted from 1st July 2019 to 31st December 2019 in the department of Obstetrics & Gynecology, Civil Hospital, Bahawalpur

The women fulfilling the following inclusion criteria were selected. All women with singleton pregnancy of cephalic presentation undergoing induction of labor at gestational age between 37-41 weeks with an intact membrane were included. Age range was from 18-40 years, & Parity was 0-5. The following women. Females with a Bishop score >6, prelabour rupture of membrane, previous history of C-section or any other uterine surgery or co morbidities, low-lying placenta and fetal growth restriction were excluded from the study. The sampling done by non-probability, consecutive sampling. The calculated sample size was 60 i.e. 30 cases in each group, with 80% power of study, 5% level of significance.

Data collection procedure: After taking permission from ethical review committee, total 60 women who were presented in said hospital, fulfilling the inclusion criteria was selected. At admission, all patients had an obstetrical ultrasound evaluation. After taking informed written consent, patients were randomly divided into two groups i.e. Group A (transcervical folley's catheter) & Group B (intracervical prostaglandin E2), by using lottery method. In group A, patient was laid in lithotomy position, the cervix was exposed with sterile Cusco's speculum and a 16 Fr Foley catheter was inserted through the external cervical os under aseptic measures. Thereafter, the balloon was inflated with 40 ml of normal saline and kept under mild traction. While in group B patients, a vaginal suppository containing 3 mg dino-prostone inserted in the posterior fornix. Oxytocin augmentation with titrating dose (4-32mIU/min) was started to both groups after 12-24 hours according to response & desired effect (expulsion of catheter, establishment of 3 strong contraction/10 minutes) achieved. In both groups, time of mean induction to delivery was measured. This all data including the demographic data was recorded on a specially designed preforma.

Data analysis: All the data was analyzed by using SPSS version 20. Age, gestational age, bishop score, parity, height, weight, BMI and induction to delivery time were presented as mean and standard deviation. Frequency and

percentages were calculated for gestational diabetes and pregnancy induced hypertension. Student 't' test was used to as a test of significance (p-value \leq 0.05)

Effect modifiers controlled through stratification. Post-stratification student 't' test was applied to see effect on mean induction to delivery time (p-value \leq 0.05)

RESULTS

In my study, age ranged from 18 to 40 years with a mean age of 31.0 ± 5.31 years .The mean age of patients in group A was 30.67 ± 5.09 years and in group B was 31.33 ± 5.58 years. Majority of the patients 38 (63.33%) were between 31 to 40 years.

Mean gestational age was 39.12 ± 1.24 weeks. The mean gestational age of group A was 39.13 ± 1.25 weeks while of group B was 39.10 ± 1.24 weeks. Majority of the patients 36 (60.0%) were 37-39 weeks of gestation.

Mean parity was 2.63 ± 1.07 . Mean BMI was 28.90 ± 2.40 kg/m² . The mean height was 1.52 ± 12.92 m and weight was 74.92 ± 12.85 kg. Mean bishop score was 2.97 ± 0.99 .Table I

In my study, time from induction to delivery in Foley catheter group (14.23 hours \pm 2.10) was significantly lower than that of PGE2 group (19.73 hours \pm 1.60) (p-value = 0.0001) as shown in Table II.

Stratification of induction to delivery time with respect to age, gestational age and parity, BMI and bishop score and stratification of induction to delivery time with respect to PIH & GDM are shown in Table III.

Table I: Distribution of different parameters of the patients in both groups

	Groups	GROUP A		GROUP B	
		Freq.	%	Freq.	%
Age	18-30	12	40	10	33.3
	31-40	18	60	20	66.6
GA(Weeks)	27-39	18	60	18	60
	40-41	12	40	12	40
Parity	0-2	16	53.3	15	50
	3-5	14	46.6	15	50
BMI	< 27	12	40	9	30
	>27	18	60	21	70
Bishop	0-2	12	40	11	36.6
	3-5	18	60	19	63.6
PIH	Yes	15	50	13	43.3
	No	15	50	17	56.6
GDM	Yes	12	40	15	50
	No	18	60	15	50

Table-II: Comparison of mean induction to delivery time between transcervical Foley's catheter and intracervical prostaglandin E2 for induction of labour.

Outcome	Group A (n=30) Mean \pm SD	Group B (n=30) Mean \pm SD	p-value
Induction to delivery time (hrs)	14.23 ± 2.10	19.73 ± 1.60	0.0001

➤ P value is 0.0001 which is statistically significant.

Table III: Stratification of induction to delivery time with respect to gestational age

		Group A		Group B		P-value
		Mean	SD	Mean	SD	
Age(yrs)	18-30	13.58	1.73	20.2	1.83	0.0001
	31-40	14.67	2.25	19.60	1.50	0.0001
GA (wks)	37-39	14.39	2.12	19.94	1.66	0.0001
	40-41	14.0	2.13	19.42	1.51	0.0001
Parity	0-2	14.63	1.86	19.60	1.64	0.0001
	3-5	13.79	2.33	19.87	1.60	0.0001
BMI (kg/m ²)	≤27	14.25	2.18	18.67	1.32	0.0001
	>27	14.22	2.10	20.19	1.50	0.0001
Bishop score	0-2	13.58	2.35	20.18	1.47	0.0001
	3-5	14.67	1.85	19.47	1.65	0.0001
PIH	Yes	14.67	1.79	20.15	1.72	0.0001
	No	14.20	2.43	19.41	1.46	0.0001
GDM	Yes	14.0	1.86	19.53	1.51	0.0001
	No	14.39	2.28	19.93	1.71	0.0001

DISCUSSION

The first step in labor induction is cervical ripening, using drugs or mechanical methods to dilate the cervix sufficiently before labor process can be initiated.

Mechanical methods of cervical ripening are old but safest method that now includes application of a cervical ripening balloon or a foley catheter. These devices apply pressure on the cervix and stimulate local release of prostaglandin.¹⁴ Compared to prostaglandin gel, these have an advantage in terms of reduced risk of uterine hyper tonus or tachysystole with an associated abnormal fetal heart rate pattern.¹⁴ currently this is the only option for a woman with a low Bishop score and who chooses induction over c-section. Another advantage is when there is an unripe cervix and there is urgent need to proceed with induction. Oxytocin can be initiated at the time of catheter insertion. This randomized controlled study has compared the mean induction time to delivery between transcervical Foley’s catheter and intracervical prostaglandin E₂ for of labour induction.

The basic characteristics of age, gestational age range in my study was matching the results of other studies (Age range from 18 to 40 years with mean age of 31 years). Majority of the patients (63%) were between 31 to 40 years of age. Mean gestational age was 39 weeks. Majority of the patients (60.0%) were 37-39 weeks of gestation .In my study, induction to delivery time in Foley catheter group (14.23 ± 2.10 hrs) is significantly lower than that of PGE₂ group (19.73 ± 1.60 hrs) (p-value = 0.0001). Ziyauddin F & co researchers found that after 12 hours both the mechanical methods had a comparable effect on the Bishop’s score and interval between induction to the delivery was longer with PGE₂ gel ,21.06 hours, as compared to Foley catheter ,18.15 hours.¹⁵

A study conducted in Sri Lanka, South Asia reinforced the findings of our study & gave a strong conclusion about the effectiveness of FC insertion method of cervical priming for induction of labour.¹⁶ It can be a recommended in low resource countries as well owing to its low cost, a high chance of vaginal delivery rate and gives good patient comfort. It is also a useful method of induction for females who have completed uncomplicated 41 weeks of gestation.¹⁶

In PROBAAT trial conducted in Netherlands, FC use resulted in fewer postpartum hemorrhage and neonatal admissions compared to the prostaglandins. It has also

showed a comparable C-section rate and costs.¹⁷

Another study using double-balloon catheter has shown greater cost-effectiveness and safety than prostaglandin 2 agents for cervical ripening and labour induction.¹⁸ The efficacy of both the methods was similar.¹⁸ The all above researchers pointed out that FC had a better efficacy, safety & cost effectiveness, as our study concluded.

Few researchers results did not matched with finding of our study result. As Das KK, in his study, pointed out that the mean duration from induction to active labour was significantly higher in the catheter group (14.08 ± 4.802 hours versus 11.92 ± 4.66 hours, p= 0.035). The mean duration from induction to vaginal delivery is 19.08 ± 6.48 hours in Foley catheter group and 17.27 ± 6.19 hours in gel group, which was statistically non-significant (p value= 0.22).¹⁹ Noor N et al recorded statistically similar induction to active labour time, but significantly longer induction-delivery time in catheter group than gel group (p < 0.01).²⁰

Henry A et al stated that PGE₂ gel is faster than Foley’s catheter in induction as they recorded higher number of patients delivering within 12 hours of admission (53% in gel group versus 28% in catheter group, p value= 0.01). However total inpatient stay was statistically insignificant (p value=0.26).²¹ Similarly Jozwiak M et al recorded significant difference in delivery time (29 hours in catheter group versus 18 hours in gel group, p value <0.0001).²² In contrast to previous studies, St Onge RD et al reported significantly shorter induction to delivery duration in the Foley group compared to PGE₂ gel group (16 ± 1.7 hours versus 21.5 ± 3.2 hours, p value =0.014).²³

Few researchers compared the misoprostol (PGE₁) with FC in terms of efficacy & induction to delivery time. Promila et al²⁴, Sheikher et al²⁵, Filho et al²⁶, and Roudsari et al²⁷ showed that there was a significantly shorter induction to delivery interval in the misoprostol group. Tuuli et al²⁸ reported that there was no significant difference in the total duration of labour in women induced with misoprostol. Prager et al²⁹ also supported our result.

CONCLUSION

This study concluded that foley catheter found to have better results for IOL in comparison with PGE₂ in reducing induction to delivery time with better safety fetomaternal profile.

Recommendation: We recommend that trans cervical Foley's catheter should be used as first line therapy for induction of labour especially in low/medium resource settings like ours because it is comparable in terms of efficacy with intra cervical prostaglandin E2.

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