

## Original Article

# Induction of Labour in Primigravidas with Foley's Catheter and Prostaglandin E2 Tablet versus Prostaglandin E2 Tablet Alone: A Randomized Control Trial

Rubaba Abid, Hasan Murtaza, Tabinda Khalid, Hamna Atta

<sup>1</sup>Assistant Prof. Obs/Gynae Rawalpindi Medical University, Rawalpindi, <sup>2</sup>Consultant Physician HITEC Hospital, <sup>3</sup>Senior Registrar Obs/Gyn DHQ hospital Rawalpindi, <sup>4</sup>Postgraduate trainee Obs/Gynae, DHQ hospital., Rawalpindi

**Correspondence:** Dr Rubaba Abid

Assistant Prof. Obs/Gynae Rawalpindi Medical University, Rawalpindi  
rubaba\_abid@yahoo.com

## Abstract

**Objective:** To compare the efficiency of Foleys catheter and Prostaglandin E2 pessary with ProstaglandinE2 alone in induction of labour in primigravidas

**Methodology:** It was a randomized controlled trial, prospective study carried out in in the obstetrics and gynaecology department of District headquarters hospital Rawalpindi affiliated with Rawalpindi Medical University from 2016 to 2017. Sample size 200 (100 in each group). Group A(ICF +PG) and group B(PG). In Group A the ICF along with prostaglandin were simultaneously used. Data was stratified for age, gestational age, induction delivery interval, duration of labour, mode of delivery and maternal and fetal complications. Post stratification both groups were compared for efficacy by using chi-square test p-value < 0.05 was considered significant.

**Results:** The parameters of maternal age gestational age, initial bishop score maternal and fetal complications were comparable in the two groups. The induction to delivery interval was seen to be less for group A as compared to group B(10.9 hours vs 13.4 hours). The number of doses required for ripening of the cervix were also less for group A than group B. The mode of delivery was spontaneous vaginal delivery in 70(69.3%) in group A whereas it was 55(55%) in group B (p-value <0.05) Caesarean section was done in 31% as compared to 9.3% for fetal distress in group A and B respectively(p value<0.05)

**Conclusion:** It can be seen that there is a greater chance of vaginal delivery with the simultaneous use of Foleys catheter with PGE2 for induction of labour, in primigravida, as compared to PGE2 used alone. Moreover the disadvantages of prostaglandins can also be overcome by this method.

**Keywords:** Prostaglandin, Foley catheter, induction of labour.

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## Introduction

Induction of labour has been practised since 'Hippocrates' original description of mammary stimulation and mechanical dilatation of the cervix. In olden times it was done for life threatening conditions but with the introduction of safer methods interventions are done for multiple other reasons.<sup>1</sup>

Induction of labour is the initiation of the process of

labour by artificial means before the onset of spontaneous labour. It is considered when the benefits of delivering are more than continuing with the pregnancy.<sup>2</sup> With changing times the reasons for induction of labour along with the methods have undergone many changes. Now even maternal request for induction is considered with no added complications like increased risk of caesarean section.<sup>3</sup>

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There are different methods of induction of labour. Mechanical as well as pharmacological. Mechanical methods cause cervical ripening by the mechanical and physical distention and stretching of the cervix which in turn causes the release of endogenous prostaglandins.

A recent study using immunoassay and immunohistochemistry showed Foley's catheter to cause changes in biochemical mediators thus affecting cervical ripening. In women who received Foley's catheter the levels of Interleukin (IL-6, IL-8), Matrix metalloproteinases, NO synthetase and hyaluronic synthetase were observed to be significantly higher. The mechanical methods are becoming popular as they are not associated with complications of hyperstimulation and fetal distress.<sup>4</sup>

Prostaglandins are hormones produced naturally by the body that are essential for the initiation of labour. They promote cervical ripening which is the pre-requisite for the onset of labour by acting on the cervical procollagenases which in turn increases hyaluronic acid that causes the softening of the cervix. Thus it facilitates cervical dilatation and effacement.<sup>5,6</sup>

Literature review shows very scarce research on comparison of prostaglandins with simultaneous use of mechanical method with prostaglandin for induction of labour.

Induction of labour in primigravida with a poor bishop has always been a dilemma. This study was conducted to compare the effectiveness and efficiency of the combined use of intracervical foleys catheter with PGE2 tablet as compared to PGE2 tablet alone, for induction of labour in primigravidas.

## Methodology

It was a randomized controlled trial, prospective study carried out in the obstetrics and gynaecology department of District headquarters hospital Rawalpindi affiliated with Rawalpindi Medical University from 2016 to 2017. Sample size 200 (100 in each group).

Inclusion criteria All primigravida needing IOL from 37 completed weeks onwards.

Exclusion criteria: All multigravidas, gestation less than 37 completed weeks, patient not giving consent A written informed consent was taken from women before any procedure undertaken for the study. The 201 patients included in this study were divided into 2 groups A(ICF +PG) and group B(PG). In Group A the ICF along with prostaglandin were simultaneously

used. Intracervical Foley's catheter of 24 FR was placed in the extra amniotic space through cervix under aseptic conditions. The bulb was inflated with 50 cc distilled water. The catheter is pulled and tapped to the thigh such that the balloon comes to lie at the internal os. Prostaglandin E2 3mg vaginal tablet was kept in the posterior fornix of the vagina which could be repeated. In Group B Prostaglandin E2 3mg was placed in posterior fornix was vagina and was repeated to improve the bishop score if bishop score did not improve on evaluation after 6 hours. Labour was monitored of both groups. The initial bishop score, mean induction to delivery interval, number of doses required, mode of delivery, maternal and fetal complications and indications for c-sections were noted.

## Results

In our study each of the 2 groups had 100 patients each. Both of them were similar in demographic details i.e age, gestational age and pre-induction bishop score.

The mean and standard deviation regarding age was  $26.66 \pm 3.7$ , in group A and  $26.59 \pm 3.4$  in group B ( $p > 0.05$ ) respectively. The mean gestational age in group A is  $40 \pm 0.573$  weeks and  $40 \pm 0.063$  weeks in group B ( $p > 0.05$ ).

The pre-induction Bishop score in group A was  $3.3 \pm 0.95$  and  $3.8 \pm 0.98$  in group B. (Table I) The mean induction to delivery interval was reduced in group A. It was  $10.96 \pm 2.9$  hours and  $13.44 \pm 4.04$  hours in group A and B respectively ( $p < 0.05$ ). (Table II)

**Table I: Comparison of Primary Bishop score of the two groups**

	Group A N=100	Group B N=100	P value
Primary Bishop Score	$3.3 \pm 0.95$	$3.8 \pm 0.96$	$> 0.05$

**Table II: Comparison of Induction to delivery interval in the two groups**

	Group A N= 100	Group B N=100	P value
Mean Induction to delivery interval(in hours)	$10.91 \pm 2.9$	$13.44 \pm 4.04$	$< 0.05$

**Table III: Indication for caesarean section in the two groups****Group of Patients \* Indication of C-Section**

		Indication of C-Section					
		fetal distress	stage failure	1 second stage failure	meconium stained liquor	Failed induction of labour	Total
Group A	Count	8	1	0	8	14	31
	% of Total	9.3%	1.2%	0.0%	9.3%	16.3%	36.0%
Group B	Count	27	2	2	10	14	55
	% of Total	31.4%	2.3%	2.3%	11.6%	16.3%	64.0%
Total	Count	35	3	2	18	28	86
	% of Total	40.7%	3.5%	2.3%	20.9%	32.6%	100.0%

The number of doses of prostaglandins required for cervical ripening were less for group A as compared to group B. In Group A 68% required one dose whereas 33% required 2 doses. In group B in 42% ripening of cervix was achieved with one dose whereas 58% required 2 doses for it. The mode of delivery however differed in the two groups. In group A caesarean section was required in 30% while 70% delivered vaginally. In group B caesarean was conducted in 45% whereas 55% delivered vaginally (p value 0.00).

The indications for caesarean section were almost similar in both the groups except fetal distress. In group A 8(8%) c-sections were for fetal distress whereas in group B 27(27%) had this indication. The rest were failure to progress in stage 1, stage 2, meconium stained liquor and failed induction which were similar in both groups as seen from the table III

## Discussion

Preferably the inducing agent should be such that it facilitates cervical ripening without initiating uterine contractions. But all induction agents release prostaglandins which cause the uterus to contract as being a part of labour initiation.

Initially foleys catheter was used by Embrey and Mollison in 1967 as a mechanical inducer of cervical dilatation<sup>7</sup>. Mechanical induction agents have the advantage of being safe, easy to use, reversible and without the complications of uterine hyperstimulation etc. They are cheaper as well.<sup>8</sup>

Nowadays the most commonly used agents for induction of labour, especially with a poor bishop score, are the prostaglandins. They are effective and facilitate delivery usually within 24 hours. Moreover, it reduces the need for augmentation with oxytocin. However,

there is an increased danger of uterine overactivity as compared to natural labour pains.<sup>9</sup>

The primary outcome measure of the effectiveness of the inducing agent in our study was the induction to delivery interval (IDI). The mean induction to delivery interval was shorter in the Group A i.e the combined group as compared to group B, 10.9 vs 13.44 hours. The same results were observed in a study by Garg and Eser.<sup>10,11</sup>

The secondary outcome measure of success was the number of patients delivering vaginally. Spontaneous vertex delivery was observed to be in a larger number of patients in the group A as compared to group B 70% vs 55% respectively. This was also seen to be consistent with previous researches.<sup>10</sup>

It was also observed that a larger number of patients required 2 doses for cervical ripening in group B as compared to group A. i.e 58% vs 33%. Moreover, the indications of caesarean section showed fetal distress to be higher in the group B. A number of researches showed prostaglandins to cause uterine hyperstimulation and fetal distress. The simultaneous use of balloon catheter seems to overcome this drawback of prostaglandins as a lesser number of doses achieve the required cervical ripening.<sup>12,13,14</sup>

It was also seen that the number of complications e.g uterine hyperstimulation, uterine rupture or immediate neonatal poor apgar score in both groups were the same. Thus, simultaneous use of mechanical and pharmacological methods can not only improve bishop score but also reduce the adverse effects of prostaglandins.<sup>12,14</sup>

## Conclusion

From this study we conclude that prostaglandin used with foleys catheter for induction has a greater chance of delivering the patient vaginally as compared to

prostaglandin alone. There is no increase in the complications with the simultaneous use of mechanical and pharmacological methods. Studies on a bigger scale are however required for more evidence and reliable deductions.

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