

## A Descriptive Study Of Mandatory Induction Of Labor Between 24-36 Weeks Of Gestation Using Extra Amniotic Foley's Catheter Alone Versus Extra Amniotic Foley's Catheter With Dinoprostone Gel (Pge<sub>2</sub>)

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### Abstract

#### BACKGROUND

Induction of labor (IOL) can be defined as the artificial initiation of labor, before its spontaneous onset, for the purpose of delivery of the fetoplacental unit<sup>1</sup>. Need for mandatory induction of preterm labor is increasing with the increasing incidence of hypertensive disorders, diabetes mellitus, oligohydramnios, intra uterine fetal deaths (IUFD), eclampsia, and lethal congenital anomalies.

#### OBJECTIVES

1. To assess the clinical profile of the patient undergoing preterm induction of labor.
2. To determine the efficacy and safety profile of the two common methods of induction, namely intrauterine Foley's catheter alone and intrauterine Foley's catheter along with intracervical Dinoprostal gel

#### METHODS

The study was conducted in Gandhi Hospital from November 2017 to April 2019. 100 women who underwent preterm mandatory induction of labor were taken into the study.

#### RESULTS

The post induction Bishops score, mean time taken for bulb expulsion, induction to delivery interval and rate of failed induction was statistically significant.

- 1) The post induction Bishops scores were 5.66 and 6.38 respectively in induction with Foleys catheter and Foleys with Dinoprostone gel groups.
- 2) The mean time for bulb expulsion was 17 and 10.95 hours respectively.
- 3) The mean time of induction to delivery interval was 24.06 and 17.82 hours respectively.
- 4) Out of 50 cases in each group 7 cases underwent deflation of Foleys bulb after 24 hours in Foleys group and 4 underwent deflation in Foleys with Dinoprostone gel group.

Thus, we conclude that preterm induction of labor by Foleys catheter with Dinoprostone gel was superior to Foleys catheter alone in terms of induction to delivery interval without affecting caesarean section rate, hyperstimulation, chorioamnionitis, endometritis and other complications.

#### CONCLUSION

Our study involved comparing the efficacy of Foleys catheter with combined method i.e., Foleys with Dinoprostone gel, showed that combined method was more superior than Foleys alone in terms of induction delivery interval without any complications when prompt delivery is necessitated.

**Key Words:** Induction of labor, Foleys Catheter, Dinoprostone gel

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### I. Introduction

Preterm birth is the one that occurs before 37 completed weeks of pregnancy. Induction of labor (IOL) can be defined as the artificial initiation of labor, before its spontaneous onset, for the purpose of delivery of the fetoplacental unit<sup>1</sup>. Need for mandatory induction of preterm labor is increasing with the increasing incidence of hypertensive disorders, diabetes mellitus, oligohydramnios, intra uterine fetal deaths (IUFD), eclampsia, and

lethal congenital anomalies. There are two categories of artificial means of cervical ripening prior to labor induction: mechanical (Foley's catheter balloon and laminaria tents etc), and pharmacological (prostaglandins PGE<sub>1</sub>, PGE<sub>2</sub>). The mechanism of Foley's catheter use consists of direct mechanical dilation of cervix and lower uterine segment, and local secretion of endogenous prostaglandins. Mechanical stretching of cervix also augments production of hyaluronic acid which may enhance cervical swelling and softening. Foley's catheter is associated with lower risk of uterine hyper stimulation, but infection may be a concern. Pharmacological preparations cause connective tissue softening, cervical effacement, and uterine activity<sup>2,3</sup>. PGE<sub>2</sub> (Dinoprostone) acts mainly on cervix due to its collagenolytic property and its widely used because its less toxic and more effective than other prostaglandins. The aim of this study is to compare the efficacy of using extra amniotic Foleys catheter alone versus extra amniotic foleys catheter with dinoprostone gel (PGE<sub>2</sub>) in mandatory induction of labor between 24-36 weeks of gestational age.

## II. Methods

It was an observational study undertaken in the Department of Obstetrics and Gynaecology of Gandhi Medical College, during the period November 2017 to October 2019. All the patients who underwent induction of labor between 24 to 36 weeks of gestational age with either single or multiple gestation with Bishop score less than 5, indicated termination for conditions like Hypertensive disorders like Severe pre-eclampsia, imminent eclampsia, antepartum eclampsia, HELLP Syndrome, severe oligohydramnios, fetoplacental insufficiency, Intra uterine fetal death and lethal Congenital anomalies to fetus not detected before were included. Women in women with term gestation, in labor, abruptio placentae, placenta previa, previous cesarean section, parity >3, premature pre labor rupture of membranes were excluded. They were randomized into two groups using simple randomization technique. A total of 100 cases were included in the study.

Women requiring induction of labor for different indications, who met the inclusion criteria were evaluated for study. After taking informed consent, detailed history was taken regarding relevant medical, surgical and obstetric conditions. Obstetric examination was performed for height of uterus, presentation, position, fetal heart and liquor. Vaginal examination was performed. Bishops score was assessed by 2 independent observers. Gestational age was confirmed by date of last menstrual period and earlier ultrasound scan reports. Ultrasound was done for assessing gestational age, liquor content and estimated fetal weight. NST was done to assess fetal condition if fetus was salvageable. Baseline investigations were sent. Women recruited in both the methods, were counselled about the procedure, after taking consent.

Under strict aseptic precautions, perineum cleaned and draped. Posterior vaginal wall retracted with sim's speculum, anterior lip of cervix held with sponge holding forceps and 16 or 18 French foleys catheter introduced intracervically. Balloon is inflated with 50 cc distilled water and pulled snugly against the internal os and the catheter is taped to the thigh under traction for a maximum of 24 hours. NST was done after the procedure for salvageable cases. After insertion, the patients were monitored for uterine contractions, fetal heart rate and expulsion of bulb. NST was repeated with interval of 6 hours. Monitoring of fetal heart was done by intermittent auscultation and uterine action by number of contractions, duration and intensity in ten minutes. In the other group allotted for Foleys with Dinoprostone gel for induction, Dinoprostone gel instilled, repeat dose of Dinoprostone instilled after 6 hrs depending upon Bishops score for maximum of three doses and time taken for bulb expulsion was noted. In both the groups, if bulb was not expelled after 24 hours, bulb was deflated and Foleys catheter was removed, Bishops score was assessed, and augmentation was done with titrated dose of oxytocin. The data collected included - indications for induction, booked/unbooked cases, gestational age, parity, modified Bishop score at the time of induction, induction-delivery interval, mode of delivery, maternal complications.

### STATISTICAL ANALYSIS:

The results were analysed using IBM-SPSS Software version 24 (IBM Corp. Released.2016 IBM SPSS Statistics for windows, IBM Version 24.0. Armonk, NY: IBM Corp.)

## III. Results

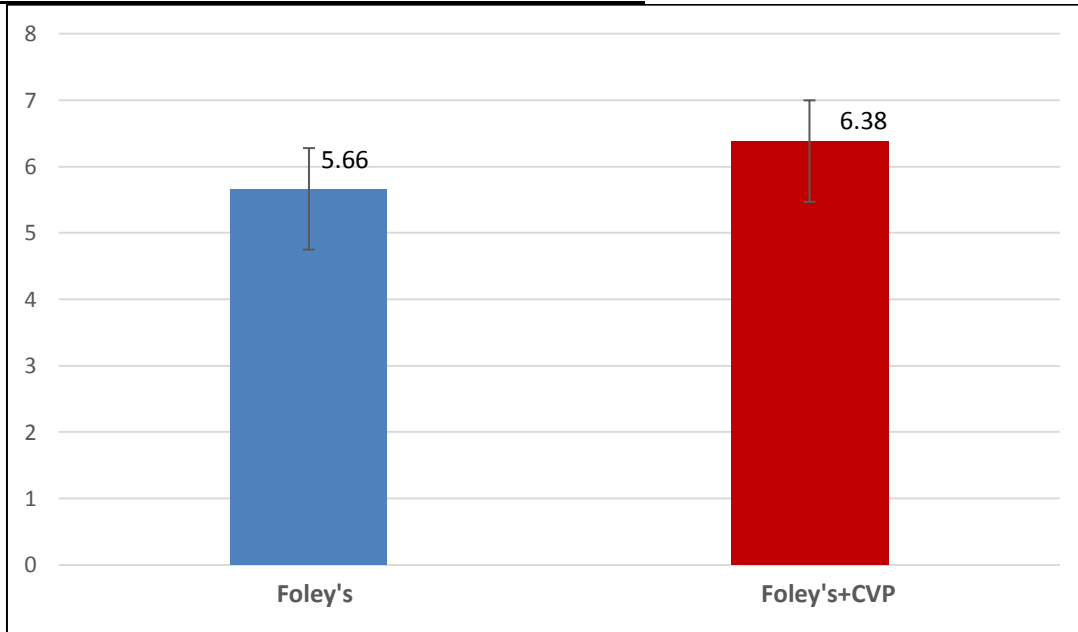
A total of 100 patients were included in the study. 50 patients were induced with Foleys catheter and the other 50 with Foleys with Dinoprostone gel. Variables of the study and their frequencies in each group along with p value are given in the table below:

Variables	Group 1 Foley's (n=50)	Group 2 Foley's + CVP (n=50)	p Value
Mean Age & Range	23.7 (19-30)	23.2 (19-36)	0.6
Nulli para	32	35	0.6
Para 1	15	11	0.6
Para 2	3	4	0.6

Booked	9	9	1
Unbooked	41	41	1
Mean Gestational Age	30.16	30.2	0.2
Pre induction Bishop's score	2.74	2.66	0.2
Post induction Bishop's score	5.66	6.38	0.008
Time of Foley's expulsion	17.04	10.95	0.01
Induction Delivery Interval (IDI)	24.06	17.82	0.00003

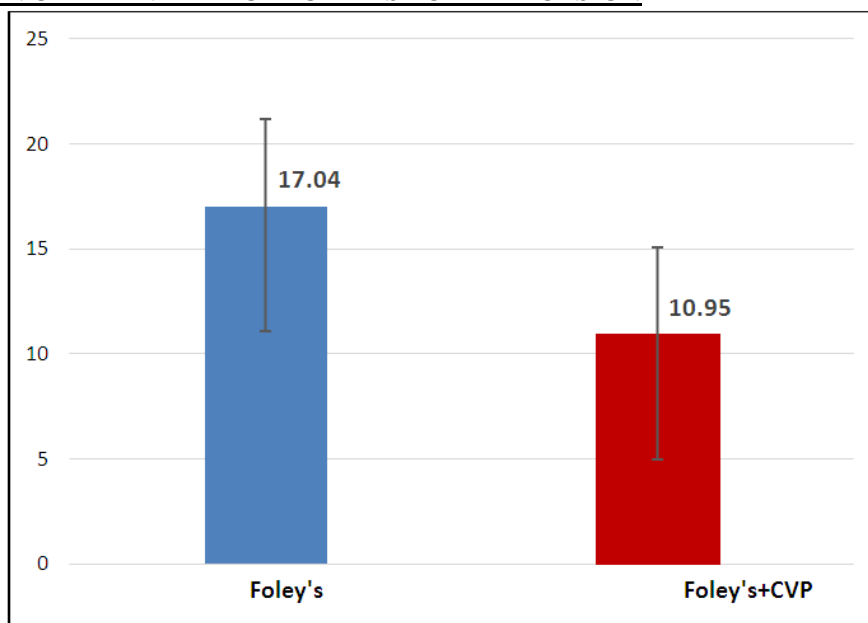
The mean age with range in both the groups was 23.7(19-30) and 23.2 (19-36) respectively. The parity, number of booked and unbooked cases, mean gestational age and pre induction bishop's score were comparable in both the cases.

**COMPARISON OF POST INDUCTION BISHOP'S SCORE**



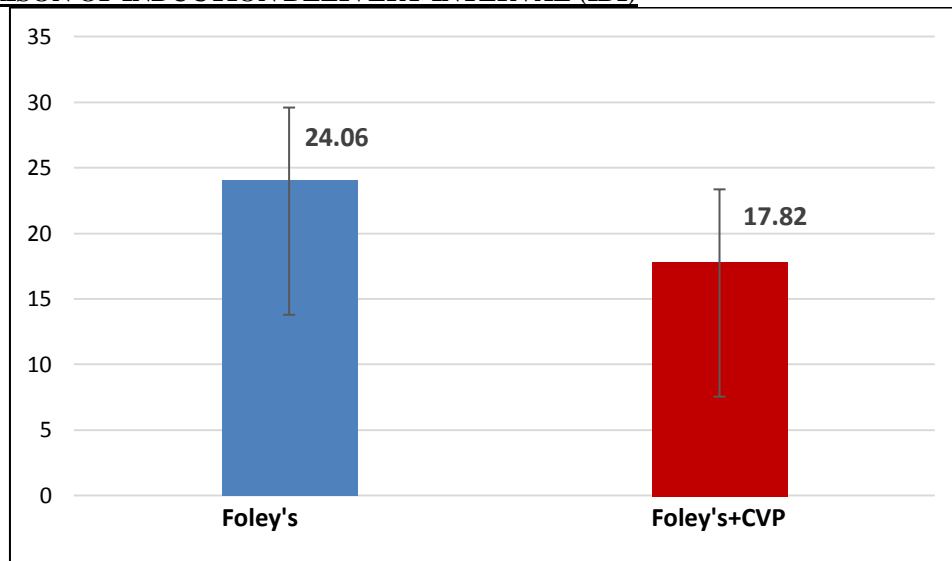
The post induction bishop's score in Foleys group ranged from 5-7 with mean of 5.66 and 5-9 with mean of 6.38 in Foleys with Dinoprostone group which is statistically significant with p value of 0.008.

**COMPARISON OF MEAN TIME OF FOLEY'S BULB EXPULSION**



The time taken for Foleys bulb expulsion ranged from 8-23 hours with a mean of 17.04 hours in Foleys group whereas 3-22 hours with a mean of 10.95 hours in Foleys with Dinoprostone group with a p value of 0.01 which is statistically significant.

**COMPARISON OF INDUCTION DELIVERY INTERVAL (IDI)**



The Induction to delivery interval ranged from 14-36 hours with a mean of 24.06 hours in Foleys group whereas 4.5-50 hours with a mean of 17.82 hours in Foleys with Dinoprostone group with a p value of 0.00003 which is statistically very significant. Bulb of Foleys was deflated after 24 hours for 7 cases in foleys group and 4 cases in Foleys with Dinoprostone group.

**IV. Discussion:**

Our study had mean gestational age of 30.2 for induction. the indications for induction were severe Oligohydramnios, Anhydramnios, lethal fetal congenital anomalies not diagnosed before, hypertensive disorders like severe preeclampsia, iminenteclampsia, antepartum eclampsia and HELLP syndrome, Intrauterine fetal death and IUGR. Study conducted by AgarwalS et al<sup>4</sup>, for preterm induction had similar indications like our study. Studies like Chowdhary et al<sup>5</sup>, Aduloju et al<sup>6</sup>, Sullivan et al<sup>7</sup> including our present study, showed statistically significant difference among the two groups with higher post induction Bishop score in combined method when compared to Foleys catheter alone. Our present study was comparable to the study conducted by Chowdhary et al.,<sup>5</sup> in relation to mean time of bulb expression which showed statistical difference between two groups in terms of time taken for bulb expulsion showing that the Foleys with Dinoprostone group to be superior to Foleys alone. Studies like Chowdhary et al<sup>5</sup>, Chung et al<sup>8</sup>, Aduloju et al<sup>6</sup>, Kashanian et al<sup>9</sup> support the result of our present study in terms of shorter induction to delivery interval compared to single method used alone. In our present study, the Foleys bulb was deflated after 24 hours of instillation if there was no spontaneous expulsion. 7 out of 50 cases in Foleys group and 4 out of 50 cases in Foleys with Dinoprostone gel group underwent bulb deflation indicating failed induction, in which delivery was achieved by other methods like vaginal misoprostol, oxytocin etc. Overall, there was statistical significance between two groups showing Foleys with Dinoprostone gel induction to be superior to Foleys group. This result is further supported by other study Sullivan et al,<sup>7</sup> in which 6 cases had failed induction when single method was adopted, whereas no case of failed induction reported in Foleys with Dinoprostone gel group. No complications were noted in either of the groups in our present study, similar to the study conducted by Chowdhary et al<sup>5</sup>, Aduloju et al<sup>6</sup>, Ugwu et al<sup>10</sup>, and Sullivan et al.<sup>7</sup> However other studies such as Greybush et al,<sup>11</sup> noted increased incidence of tachysystole in combined group of induction. Chung et al<sup>8</sup> reported infections to be more frequent with combined method of induction. Chorioamnionitis was seen in 21% of patients with combined group whereas 9% with foleys alone and 6% with PGE<sub>1</sub> (3 hourly). Hence from the above discussion, we can say that that there was no statistical difference among two groups under the study in terms of mean age of patient, parity, gestational age, indications for induction of labor, pre induction Bishops score, neonatal outcome and complications. However, the post induction Bishops score, mean time taken for bulb expulsion, induction to delivery interval were statistically significant indicating superiority of combined Foleys with Dinoprostone gel group to be superior to Foleys group alone.

## V. Conclusion

Preterm induction of labor has become mandatory in current obstetric practice, with increasing incidence of hypertensive disorders like antepartum eclampsia, severe pre-eclampsia, imminent eclampsia and HELLP Syndrome, intra uterine growth restriction. Irregular antenatal checkups resulting in late detection of lethal fetal anomalies and intrauterine fetal deaths are also major contributing factors for preterm mandatory induction of labor. Effective antenatal care, anticipation, early referral, prompt management and timely decision for induction of labor are important for both maternal and neonatal outcome. Our study involved comparing the efficacy of Foleys catheter with combined method i.e., Foleys with Dinoprostone gel, showed that combined method was more superior than foleys alone in terms of induction delivery interval without any complications when prompt delivery is necessitated.

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