

## Research Article

## Dinoprostone Gel versus Intra-cervical Foley's Catheter for Pre-induction Cervical Ripening: An audit

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### Abstract

**Objective:** to compare the efficacy and safety of the inexpensive mechanical method of induction Foley's catheter to the more established pharmacological agent Intracervical Dinoprostone (Prostaglandin E2) gel.

**Methods:** The present prospective randomised control study was carried out on 200 women with a term singleton pregnancy in cephalic presentation, with an unfavourable cervix and a valid indication for induction of labour. The patients were randomly allocated using the chit method to either Foley's catheter [group A, n=100] or PGE2 gel [group B, n=100]. Augmentation with oxytocin was done if required and labor was closely monitored till delivery and the perinatal outcome and maternal side effects was recorded. Quantitative variables were compared using unpaired t-test/Mann-Whitney Test and qualitative variables were compared using Chi-Square test /Fisher's exact test. Analysis was done using Statistical Package for Social Sciences (SPSS) version 21.0

**Result:** The cesarean section rate did not show a significant difference between the Foley's group(18%) and PGE2 group(11%) The incidence of fetal distress, Meconium stained liquor and APGAR score <7 at 5 minutes was significantly with PGE2 as compared to group A. (P<.05) Incidence of hyperstimulation of uterus was reported in 6% women who received PGE2 as compared to none in Foley's group. The induction delivery interval did not show any significant difference between the two groups.

**Conclusion:** In women undergoing induction of labour at term in resource constraint set ups like ours, Foley catheter is a good alternative to the more established prostaglandin E2 gel, with good efficacy and better neonatal and maternal safety profile.

**Keywords:** catheters, cervical ripening, dinoprostone, labor, induced, prostaglandins.

### Abstrak

**Tujuan:** untuk membandingkan kemanjuran dan keamanan metode mekanis induksi kateter Foley yang murah dengan gel agen farmakologi Intracervical Dinoprostone (Prostaglandin E2) yang lebih mapan.

**Metode:** Studi kontrol acak prospektif ini dilakukan pada 200 wanita dengan kehamilan tunggal cukup bulan dalam presentasi kepala, dengan serviks yang tidak baik dan indikasi yang valid untuk induksi persalinan. Para pasien secara acak dialokasikan menggunakan metode chit ke kateter Foley [grup A, n=100] atau gel PGE2 [grup B, n=100]. Augmentasi dengan oksitosin dilakukan jika diperlukan dan persalinan dimonitor secara ketat sampai melahirkan dan hasil perinatal serta efek samping maternal dicatat. Variabel kuantitatif dibandingkan menggunakan uji-t tidak berpasangan/Uji Mann-Whitney dan variabel kualitatif dibandingkan menggunakan uji Chi-Square/Fisher's tes eksak. Analisis dilakukan dengan menggunakan Statistical Package for Social Sciences (SPSS) versi 21.0

**Hasil:** Tingkat operasi caesar tidak menunjukkan perbedaan yang signifikan antara kelompok Foley (18%) dan kelompok PGE2 (11%) Insiden gawat janin, cairan bernoda Mekonium dan skor APGAR <7 pada 5 menit secara signifikan dengan PGE2 dibandingkan dengan kelompok A. (P<.05) Insiden hiperstimulasi uterus dilaporkan pada 6% wanita yang menerima PGE2 dibandingkan dengan tidak ada pada kelompok Foley. Interval pengiriman induksi tidak menunjukkan perbedaan yang signifikan antara kedua kelompok.

**Kesimpulan:** Pada wanita yang menjalani induksi persalinan cukup bulan dalam pengaturan kendala sumber daya seperti kami, kateter Foley adalah alternatif yang baik untuk gel prostaglandin E2 yang lebih mapan, dengan kemanjuran yang baik dan profil keselamatan ibu dan bayi yang lebih baik.

**Kata kunci:** kateter, pematangan serviks, dinoprostone, persalinan, diinduksi, prostaglandin

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## INTRODUCTION

Induction of labor is indicated in many fetal and maternal indications in modern obstetrics. The frequency of labor induction in the United States was 31.4 percent in 2020, more than tripling since 1990 when it was 9.5 percent.<sup>1</sup> In developing countries like India the rates are generally lower, but in some settings, they can be as high as those observed in the United States.<sup>2</sup> The success of induction of labor is largely dependent on the state of the cervix. Hence, cervical ripening is a prerequisite for successful induction of labor and for lowering the cesarean section rate. Consensus is yet to be reached regarding the ideal method for cervical ripening. There are a variety of methods of cervical ripening available, which can be pharmacological or mechanical. Pharmacological agents used for cervical ripening include prostaglandins (PGE1 & PGE2). Intracervical PGE2 (Dinoprostone) gel is most commonly used in present day obstetric practice.<sup>3</sup> Prostaglandins are derivatives of prostanoid acid and act as local hormones. They have direct effect on the production of procollagenase which is a precursor of collagenase, decreases collagen & increases hyaluronic acid which in turn softens the cervix and helps in cervical ripening, effacement and dilatation. While PGE2 reduces the likelihood of caesarean section compared with placebo, it increases the risk of uterine hyperstimulation with fetal heart changes.<sup>4</sup> It is contraindicated in patients of asthma and those allergic to prostaglandins, is expensive and has to be refrigerated for storage.

Intracervical Foley's catheter and. Hygroscopic dilator (laminaria tent) are the commonly available mechanical methods available for cervical ripening. In the recent years there is a renewed interest in induction of labor using Foley's catheter mostly because of lesser side effects due to hyper stimulation of uterus seen with prostaglandins. Ripening of cervix may be achieved by introduction of trans-cervical Foley's catheter. It causes mechanical dilatation of cervix and stimulates endogenous release of prostaglandins by stripping the fetal membranes and release of lysosomes from decidual cell.

Foley's catheter is a cheap and easily available but under utilised method for cervical ripening with hardly any neonatal or maternal risks. Hence, the aim of this study is to increase the data for safety and efficacy of use of Foley's catheter for

preinduction cervical ripening, so that its use can be increased in resource constraint setups.

## METHODS

The present prospective randomised comparative study was carried out on 200 pregnant women admitted to the labor room of Dr. BSA hospital between November 2017 to March 2019 for labor induction after a written consent. The study was approved by the ethical committee of our institute. Detailed history was taken and general physical & systematic and obstetric examination was done. Investigations were recorded. inclusion criteria; >37 weeks period of gestation, singleton pregnancy, intact membranes, cephalic presentation, Valid indication of induction of labour like IUGR, oligohydramnios, postdatism, hypertensive disorder of pregnancy, Gestational diabetes mellitus and intra hepatic cholestasis of pregnancy, and bishop score less than 6. Exclusion criteria; scarred uterus, malpresentation, chorioamnionitis, antepartum hemorrhage, multiple pregnancies, and CPD or any other contraindication of vaginal delivery.

The patients were randomly allocated using the chit method to either Foley's catheter [group A, n=100] or PGE2 gel [group B, n=100].

Group A- After assessing FHR and Bishop score. Under all aseptic precautions Foleys catheter (No.16F) was inserted into endocervical canal extra amniotically. Tip of catheter was placed beyond internal cervical os. Bulb of catheter was inflated with 60 ml normal saline and downward tension was created by taping the catheter to the thigh. Fetal heart rate and uterine contraction were monitored every 2 hours. Bishop's score was measured after 12 hours or whenever Foley's catheter is expelled whichever was earlier. If required, augmentation with oxytocin was done.

Group B- After assessing FHR and bishop's score, 0.5mg PGE2 gel in 3 gm base (dinoprostone) was instilled intracervically. Thereafter, woman was instructed to lie in left lateral position for 30 min. FHR and uterine contraction was monitored after PGE2 gel instillation and Bishop's score was assessed after 6 hours. If Bishop's score was not favorable after 6 hours, repeat dose of PGE2 gel was instilled. Reassessment was done to see change in Bishop's score after 12 hours. Augmentation with oxytocin was done if required. Woman was followed up till delivery and perinatal outcome and maternal adverse effects were recorded.

Categorical variables were presented in number and percentage (%) and continuous variables were presented as mean  $\pm$  SD and median. Normality of data was tested by Kolmogorov-Smirnov test. If the normality is rejected then non parametric test was used. Statistical tests were applied as follows; quantitative variables were compared using unpaired t-test/Mann-Whitney Test (when the data sets were not normally

distributed) between the two groups, qualitative variables were compared using Chi-Square test /Fisher's exact test. A p value of  $<0.05$  was considered statistically significant. The data was entered in MS EXCEL spreadsheet and analysis was done using Statistical Package for Social Sciences (SPSS) version 21.0

## RESULTS

**Table 1.** Comparison of Demographic Characteristics and Pre-induction Bishop Score between the Two Groups

Demographic Characteristic	Group		P-value
	A(n=100)	B(n=100)	
Age(Mean $\pm$ SD	23.77 $\pm$ 3.20	23.47 $\pm$ 3.34	0.45
Primigravida (No & %)	71(71)	79(79)	0.19
Booked/Unbooked	69(69)	74(74)	0.43
Period of gestation	39.61 $\pm$ 1.16	39.83 $\pm$ 1.19 weeks	$<0.05$
Pre-induction Bishop	1.97 $\pm$ .93	2.18 $\pm$ 1.31	0.1

Demographic parameters and pre induction bishop score in the two groups were comparable as shown in Table 1.

**Table 2.** Comparison of Mode of Delivery between Groups

Mode of delivery	Group		Total	P-value
	A(n=100) (%)	B(n=100) (%)		
Forceps delivery	2 (2.00)	0 (0.00)	2 (1.00)	0.147
LSCS	11 (11.00)	18 (18.00)	29 (14.50)	
Vaginal	87 (87.00)	82 (82.00)	169 (84.50)	
Total	100 (100.00)	100 (100.00)	200 (100.00)	

No significant difference was seen in the mode of delivery between the two groups. ( $P>.05$ ) Majority of patients in both the groups had vaginal delivery; 87% in group A and 82% in group B.

**Table 3.** Fetal and Neonatal Outcome Parameters in the Two Treatment Groups

	Group		Total	P-value
	A (n=100)	B (n=100)		
Fetal distress	92 (92.00)	85 (85.00)	177 (88.50)	0.018
Meconium stained liquor	7.56 $\pm$ 0.9	7.25 $\pm$ 1.11	7.4 $\pm$ 1.02	0.030
APGAR at 1 minute $<7$	8 (8.00)	15 (15.00)	23 (11.50)	0.
APGAR at 5 minute $<7$	3 (3.00)	14 (14.00)	17 (8.50)	0.009
NICU admission	6 (6.00)	14 (14.00)	20 (10.00)	0.059

Incidence of fetal distress, Meconium stained liquor and APGAR score  $<7$  at 5 minutes was significantly more in babies in group B as compared to group A. ( $P<.05$ )

**Table 4.** Obstetric Outcome Criteria for the Two Groups. Values are Given as n % or Mean  $\pm$  Standard Deviation

	Group		P-value
	A(n=100)	B(n=100)	
Need for augmentation	100 (100)	72 (72)	0.0008
Induction delivery interval in hrs	18.42 $\pm$ 4.94	16.64 $\pm$ 7.98	0.06
Hyperstimulation	0 (0.00)	6 (6.00)	0.029

In group A, all the patients needed augmentation whereas in group B, 72% of patients needed augmentation. Induction delivery time although longer in group A as compared to group B, the difference was not statistically significant.

## DISCUSSION

In the present study, the primary outcome was caesarean section rate. The caesarean section rate was lesser in group A (18%) as compared to group B (11%) but the difference was not statistically significant. Majority of patients in both the groups had vaginal delivery; 87% in group A and 82% in group B. Maternal and neonatal outcomes were better in group A in our study. The incidence of fetal distress, Meconium stained liquor and APGAR score <7 at 5 minutes was significantly more in babies in group B as compared to group A. ( $P < .05$ ) Incidence of hyperstimulation of uterus was reported in 6% women in group B as compared to none in group A. However, the need for augmentation with oxytocin was more in group A ( $p = 0.00001$ ). The induction delivery interval group A was longer than B but the difference was not statistically significant.

In meta-analysis with 3,437 women where in 1,711 participants received Foley's catheter and 1,726 participants received prostaglandins.<sup>5</sup> Both groups had a similar risk of cesarean section, vaginal delivery in 24 h or less, 5 min Apgar score less than 5, and arterial cord pH level less than 7.10. The Foley's group had a higher risk of oxytocin augmentation and the prostaglandins group had a higher risk of neonatal ICU admission.

In a systematic review including nine studies (1866 patients) both the double-balloon catheter and PGE2 agents were found to be comparable with regard to rate of caesarean section (RR 0.92; 95% CI 0.79, 1.07), vaginal delivery within 24 hours (RR 0.95; 95% CI 0.78, 1.16) and maternal adverse events, but the risk of excessive uterine activity (RR 10.02; 95% CI 3.99, 25.17) and need for neonatal intensive care

unit admissions (RR 1.31; 95% CI 1.01, 1.69) were significantly increased in women who received PGE2 agents.<sup>6</sup>

A randomized, comparative study found no significant difference in the side effects and caesarean section between the Foley's catheter and PGE2 group. The induction to delivery interval was 16.01  $\pm$  5.50 h in Foley's catheter group and 16.85  $\pm$  3.81 h in PGE2 ( $p = 0.073$ ).<sup>7</sup>

In a comparative study on multiparous women<sup>8</sup>, the cesarean section rate was similar among the Foley group (9.5%), PGE2-CR group (9.6%;  $P = 0.970$ ), and PGE2-gel group (11.8%;  $P = 0.664$ ). Women in the Foley group had a significantly shorter ripening-to-delivery interval compared with women in the PGE2-CR group (16.2  $\pm$  9.2 hours vs. 27.0  $\pm$  14.8 hours;  $P < 0.001$ ) and were more likely to deliver within 12 hours.

In a randomized control trial from Israel<sup>9</sup>, the time to active labor was significantly shorter in the Foley's group compared with the dinoprostone group, but required more oxytocin administration. The rate of vaginal delivery was the same in both the groups. A lower rate of cesarean section was found only in nulliparous women in the Foley's group. The neonatal outcome was favorable and similar in both groups.

In a comparative study from France on obese women,<sup>10</sup> a double-balloon catheter was significantly associated with an efficient cervical ripening compared to vaginal dinoprostone (aOR 7.81, 95% CI 2.58-23.60). No difference was observed in cesarean section rate (39.1% in each group;  $P = 0.96$ ) and in mean induction time to vaginal delivery (34.5h in the balloon group vs 36.5h in the dinoprostone group;  $P = 0.53$ ). Maternal and neonatal outcomes were similar.

In a study comparing PGE2 insert vs Foley's catheter for labor induction, no significant difference was noted in the mode of delivery or induction delivery interval between the two groups. However, PGE2 insert was found to be associated with more cases of tachysystole and requirement of a second method of cervical ripening.<sup>11</sup>

**CONCLUSION**

In our study there was no significant difference in the caesarean section rate and induction delivery interval in the two groups. The need for oxytocin augmentation was more in the Foley's group. Perinatal outcome was better and maternal adverse effect like hyperstimulation was less in the Foley's catheter group. In a developing country like India with limited resources, Foley's catheter may be advantageous for induction of labor as it is safer with regard to fetal outcome, which is advantageous in a resource constraint setting with higher patient load where continuous electronic fetal monitoring is not available. Foley's catheter has low cost and does not require special storage facility like PGE2 gel (which requires refrigeration).

**LIMITATION**

Larger sample size could have been analysed.

**CONFLICT of INTEREST /FUNDING**

None

**REFERENCES**

1. Osterman MJK, Hamilton BE, Martin JA, et al. Births: Final Data for 2020. *Natl Vital Stat Rep.* 2022; 70:1.
2. WHO Recommendations Induction of labor at term or beyond. 2018:4.
3. Marconi A. Recent advances in the induction of labor. *F1000 Res.* 2019 Oct 30;8:F1000 Faculty Rev-1829.
4. Good Clinical Practice Recommendations FOGSI-ICOG. Induction of Labor: Good Clinical Practice Recommendations. 2018
5. Yue L, Zhigang H, Liwen S, Jiawen Z, Jinbo W et al. Foley's catheter balloon versus prostaglandins for cervical ripening and labor induction: A systematic review and meta-analysis. *Int. J. Clin Exp Med* 2016; 9(4):7573-84.
6. Du Y, Zhu L, Cui L, Jin B, Ou J. Double-balloon catheter versus prostaglandin E2 for cervical ripening and labour induction: a systematic review and meta-analysis of randomised controlled trials. *BJOG.* 2017;124(6):891-99. doi: 10.1111/1471-0528.14256.
7. Rajeswari A, Sivaranjan P. Comparative Study of Intra-Cervical Foley's Catheter and PGE2 Gel for Pre-Induction Cervical Ripening. *JMSCR.* 2017;5(8) 2450-5.
8. Manly E, Hirsch L, Moloney A, et al. Comparing Foley Catheter to Prostaglandins for Cervical Ripening in Multiparous Women. *J Obstet Gynecol Can.* 2020;42(7):853-60.
9. Barda G, Ganer Herman H, Sagiv R, Bar J. Foley catheter versus intravaginal prostaglandins E2 for cervical ripening in women at term with an unfavorable cervix: a randomized controlled trial. *J Matern Fetal Neonatal Med.* 2018;31(20):2777-81
10. Grange J, Dimet J, Vital M, Le Thuaut A, Ducarme G. Double-balloon catheter compared to vaginal dinoprostone for cervical ripening in obese women at term]. *Gynecol Obstet Fertil Senol.* 2017;45(10):521-7.
11. Blair R, Harvey MA, Pudwell J, Bougie O. Retrospective Comparison of PGE22 Vaginal Insert and Foley Catheter for Outpatient Cervical Ripening. *J Obstet Gynecol Can.* 2020;42(9):1103-10.