



COMPARATIVE STUDY OF EFFICACY OF INTRACERVICAL FOLEY'S WITH INTRACERVICAL PGE2 GEL VS. PGE2 GEL ALONE FOR INDUCTION OF LABOUR AT TERM GESTATION

Dr Soumya B G¹, Dr Chetana Rao N², *Dr Shashikumar N S³

^{1,2}. Assistant professor, Department of obstetrics and Gynaecology, Subbaiah Institute of Medical Sciences and Research Centre, Shivamogga, Karnataka.

^{*3}. Associate professor, Department of obstetrics and Gynaecology, Subbaiah Institute of Medical Sciences and Research Centre, Shivamogga, Karnataka.

***Corresponding Author:** Dr Shashikumar N S

*Associate professor, Department of obstetrics and Gynaecology, Subbaiah Institute of Medical Sciences and Research Centre, Shivamogga, Karnataka.

ABSTRACT:

Background: Induction of labour is indicated when continuing pregnancy poses risk to the mother or fetus, and success depends largely on cervical ripening. Both mechanical (Foley's catheter) and pharmacological (PGE2) methods are used, but evidence on their combined use at term remains limited.

Objectives: To compare intracervical Foley's catheter with PGE2 gel versus PGE2 gel alone for induction of labour at term in terms of: induction–delivery interval, need for oxytocin augmentation, mode of delivery, and fetal outcome including Apgar scores.

Methods: A prospective observational study was conducted in the Department of Obstetrics and Gynecology, subbaiah institute of medical sciences and research centre, Shivamogga over one year, including 100 women with singleton, cephalic, term pregnancies (gestation >36 weeks) and unfavorable cervix who required induction. Eligible women were randomized into Group A (n=50, simultaneous transcervical Foley's catheter plus intracervical 0.5 mg PGE2 gel) and Group B (n=50, PGE2 gel alone, repeatable 6-hourly up to 3 doses), and followed for Bishop score change, induction–delivery interval, oxytocin use, mode of delivery, and neonatal Apgar scores.

Results: Most women in both groups were 21–30 years and primigravida, with comparable baseline characteristics and pre-induction Bishop scores (~3.4). After induction, Bishop scores of 6–10 occurred in 94% of Group A versus 82% of Group B ($P<0.045$), and mean Apgar scores were significantly higher in Group A at 1 minute (7.94 ± 0.24 vs 7.76 ± 0.43 , $P=0.011$) and 5 minutes (9.00 ± 0.00 vs 8.80 ± 0.40 , $P=0.001$).

Conclusion: Combined use of intracervical Foley's catheter with PGE2 gel yields significantly better cervical ripening and neonatal Apgar scores than PGE2 gel alone for term induction of labour. This combination appears more effective and safer, offering favourable maternal and fetal outcomes in women requiring induction at term.

Keywords: induction of labour, cervical ripening, intracervical Foley's catheter, PGE2 gel, term pregnancy, Bishop score, Apgar score, obstetric outcomes

INTRODUCTION:

The term "induction of labour" refers to the stimulation of contractions prior to the spontaneous commencement of labour, with or without ruptured membranes that cause the cervix to gradually dilate and efface¹. The baby should ideally be born vaginally as a result of this. Cervix compliance, consistency, and configuration are critical to the effectiveness of labour induction².

Induction of labour is advised when extending the pregnancy is not beneficial to the fetus and could put the mother or fetus in danger. Due to enhanced antepartum fetal observation, the incidence of induction has grown recently. In contemporary obstetric practice, this is one of the most common interventions.

There are various methods for inducing labor, which encompass both mechanical and pharmacological agents for cervical ripening. Mechanical methods consist of the transcervical Foley's catheter and the double-balloon catheter. Pharmacological methods include the use of prostaglandins, antiprogesterins, and nitric oxide donors. Each of these agents has its advantages and disadvantages³. The induction using an intracervical Foley's catheter creates mechanical distension in the lower segment of the uterus, which stimulates the activation of phospholipase A. This process leads to the production of arachidonic acid, which is subsequently converted into prostaglandins³.

Prostaglandins, which are derivatives of prostanoic acid, function as local hormones. They stimulate the production of procollagenases that break down collagen, making the cervix softer and aiding in cervical effacement and dilation. Mechanical methods pose a lower risk of uterine hyperstimulation compared to pharmacological ones, but they may result in a longer interval between induction and delivery. Cervical ripening is associated with a decreased incidence of cesarean sections³. Carbone et al. advocated for the concurrent or sequential use of multiple methods for cervical ripening⁴. Currently, there is a scarcity of research regarding the simultaneous application of prostaglandins and mechanical methods for labor induction. Therefore, this study aims to evaluate the effectiveness of transcervical foleys combined with PGE2 gel compared to using PGE2 gel alone for inducing labor at full term.

OBJECTIVES:

The purpose of the study is to assess the efficiency of intra cervical Foley's with PGE2 gel Vs. PGE2 gel alone for labour induction at term gestation in terms of Induction delivery time, Need for augmentation with oxytocin, Mode of delivery, Fetal outcome.

MATERIAL & METHODS:

Study Design: A prospective observational study.

Study area: Department of obstetrics and Gynaecology, Subbaiah institute of medical sciences and research centre, Shivamogga.

Study Period: 1 year.

Study population: Patients who are admitted with singleton pregnancy with term pregnancy for induction of labour are selected for the study in the Obstetrics and Gynaecology Department.

Sample size: The study consisted of a total of 100 subjects.

Sampling method: Simple random sampling method.

Inclusion criteria:

- 1) Singleton pregnancy.
- 2) Gestational age >36 weeks
- 3) Cephalic presentation.
- 4) Intact membranes.
- 5) Bishop's score.
- 6) No signs of infection.
- 7) Clinically adequate pelvis

Exclusion criteria:

- 1) Patients with premature rupture of membranes.
- 2) Scarred uterus.
- 3) Known hypersensitivity to prostaglandins.
- 4) Multiple pregnancies.
- 5) Bishop's score >5
- 6) Malpresentation.
- 7) APH.

Ethical consideration: Institutional Ethical committee permission was taken before the commencement of the study.

Study tools and Data collection procedure:

- ✓ Detailed history.
- ✓ General physical examination.
- ✓ Abdominal examination.
- ✓ Relevant laboratory investigations.

The pregnant women with Gestational age > 36 weeks attending the Obstetrics and Gynaecology Department, over a period of one year meeting the inclusion criteria were taken into the study.

The pregnant women in the study are subjected to detailed history, thorough clinical and general examination. Relevant investigations along with NST done. After informed consent, appropriate counselling of the mother regarding indication, risks, benefits and alternatives to induction of labour are explained, the patients are then randomized to either Group A or Group B.

Group A comprises of 50 pregnant women posted for labour induction with simultaneous use of Foley's catheter with intracervical PGE2 gel. Group B comprises of 50 pregnant women posted for labour induction with sequential use of PGE2 gel alone.

After confirming the gestation, cephalic presentation and presence of fetal heart sounds, the patients are examined, and cervical status is assessed using Modified Bishop's score.

Group A: Under aseptic precautions and after giving prophylactic antibiotics, women are kept in lithotomy position. Sim's speculum is inserted into the vagina to gain access to the cervix. The cervix is cleansed with antiseptic solution before inserting the Foley's catheter. 18F foley's catheter was introduced into the cervical canal then, beyond the internal os and its balloon is inflated with 30-60ml sterile water. The distal end of the catheter was taped to the medial part of the thigh to provide traction. There is simultaneous insertion of 0.5mg of PGE2 gel in prefilled syringe into cervical canal.

Group B: Under aseptic precautions and after giving prophylactic antibiotics, the patient kept in lithotomy position. With the help of Sims speculum, the anterior cervical lip is visualized and held with the sponge holding forceps. 0.5mg of PGE2 gel is administered into the canal of the cervix just below the level of internal os. Reassessment has to be done after 6 hours. The dose can be repeated after 6 hours if required maximum up to 3 doses. All patients are monitored clinically for the advancement of labour and fetal wellbeing. Bishop's score was recorded pre-induction and post-induction after 6 hours of induction. Doses required for induction, induction delivery interval, mode of delivery and associated fetal complications were also noted.

STATISTICAL ANALYSIS:

The data are tabulated in Microsoft excel and analyzed with IBM SPSS V.24 software. The continuous variables are presented with mean $\pm$ standard deviation. The categorical variables are presented with frequency and percentage. The results have been presented with appropriate tables and diagrams.

OBSERVATIONS & RESULTS:

Table 1: the age distribution of pregnant women.

Age in years	Group A	Group B	Total
<20	2(4%)	3(6%)	5(5%)
21-30	45(90%)	43(86%)	88(88%)
31-40	3(6%)	4(8%)	7(7%)
Total	50(100%)	50(100%)	100(100%)
Mean $\pm$ SD	24.48$\pm$ 2.83	24.92$\pm$ 3.49	

Pregnant women with age <20 years are 2 (4%) pregnant women in Group A and 3 (6%) pregnant women in Group B. The bulk of pregnant women in these groups are between the age group of 21 to 30 years, constituting 45(90%) in group A, and 43(86%) in group B. Only 6% of the women in group A were aged more than 30 years, while 8% in group B were aged more than 30 years. The mean maternal age in group A is 24.48 $\pm$ 2.83 and in group B is 24.92 $\pm$ 3.49 (P=0.825) statistically not significant.

Primigravida constitutes 76% in group A and 70% in group B. Multigravida constitutes 24% in group A and 30% in group B, individually. The P-value -0.499 which is statistically not significant.

The majority of the women in the trial were in the 38–39-week gestational age category, accounting for 58 percent in the group A and 46 percent in the group B, respectively. In the Group A and Group B, respectively, 8% and 6% of the women were in the 38-week gestational age group. The average period of gestation in group A was 39 $\pm$ 3.14 The average period of gestation in group B was 39.4 $\pm$ 5.49 P-value is statistically not significant.

Table 2: distribution of indication of induction in the patients studied in two groups

Indications	Group A	Group B	Total
Postdated pregnancy	19(38%)	22(44%)	41(41%)
Gestational HTN	8(16%)	6(12%)	14(14%)
Mild preeclampsia	6(12%)	7(14%)	13(13%)
Oligohydramnios	5(10%)	4(8%)	9(9%)
GDM	4(8%)	4(8%)	8(8%)

Severe pre-eclampsia	5(10%)	2(4%)	7(7%)
RH (-ve) pregnancy	1(2%)	2(4%)	3(3%)
IUGR	2(4%)	3(6%)	5(5%)
Total	50(100%)	50(100%)	100(100%)

Induction of labour is most commonly used for postdated gestation which accounts for 19 (38 percent) in group A and 22 (44 percent) in group B. Gestational hypertension is the next most common diagnosis, accounting for 8 (16%) in group A and 6 (12%) in group B. There are 6(12%) cases of mild pre-eclampsia and 5(10%) cases of severe pre- eclampsia in group A. There were 7 (14%) cases of mild pre- eclampsia and 2(4%) cases of severe pre- eclampsia in group B.

The majority of women in both groups had a Bishop Score of 3 or 4 prior to induction. Pre-induction Bishop scores of 3 and 4 were found in 16 cases (32%) and 20 cases (40%) in group A, respectively. 15 patients (30%) in group B had Bishop scores of 3 and 4, respectively prior to induction.

Table 3: Post induction bishop score distribution of patients studied in two groups

Post induction bishop score	Group A	Group B	Total
1-5	1(2%)	8(16%)	9(9%)
6-10	47(94%)	41(82%)	88(88%)
>10	2(4%)	1(2%)	3(3%)
Total	50(100%)	50(100%)	100(100%)
Mean ± SD	7.78± 1.474	7.4± 1.45	

P-value is <0.045, statistically significant,

After the induction, Bishop's score in both study groups ranged from a low of 4 to a high of 10 in group A, and from a low of 3 to a high of 10 in group B. A maximum number of women in group A had a Bishop score of 6-10, accounting for 94 percent of total cases and 82 percent in group B. P-value is statistically significant.

Table 4: Dose required distribution of patients studied in two groups

Number of necessary dosages of PGE2 gel	Group A	Group B	Total
1	40(80%)	15(30%)	55(55%)
>2	10(20%)	35(70%)	45(45%)
Total	50(100%)	50(100%)	100(100%)

P-value: < 0.00001., statistically significant

In group A, 80% of cases required one dose of PGE2 gel whereas 20% cases required greater than one dose of PGE2 gel. In group B, 30% cases required one dose of PGE2 gel whereas 70% cases required more than one dose of PGE2 gel.

Pregnant women of 47% did not require augmentation of labour in both sets of patients. Only 10% of the pregnant women required augmentation for >6hours.

Table 5: Mode of delivery distribution of patients studied in two groups

Mode of delivery	Group A	Group B	Total
Full-term normal delivery	40(80%)	32(64%)	72(72%)
LSCS	10(20%)	18(36%)	28(28%)
Total	50(100%)	50(100%)	100(100%)

P=0.052+, significant, Chi-Square test

The proportion of women in both groups had vaginal deliveries, with 40 (80%) in group A and 32 (64 %) in group B. LSCS was performed on 20% of pregnant women in Group A and 36% of pregnant women in Group B. P-value is statistically significant.

Table 6: Induction delivery interval distribution of patients studied in two groups

Induction delivery interval	Group A	Group B	Total
Within 12hrs	14(28%)	12(24%)	26(26%)

12-24hrs	32(64%)	32(64%)	64(64%)
>24hrs	4(8%)	6(12%)	10(10%)
Total	50(100%)	50(100%)	100(100%)
Mean ± SD	13.82± 4.984	15.3± 4.781	

P=0.133, Not significant, student t-test

The mean IDI in Group A is 13.82 ±4.98 hours and 15.3 ± 4.781 hours in group B. The P-value was 0.133 which is statistically not significant. Group A showed shorter IDI than group B.

Table 7: Apgar score distribution of patients studied in two groups

Apgar score	Group A (n=50)	Group B gel(n=50)	Total (n=100)	P value
1 min				
• <5	3(6%)	5(10%)	0(0%)	0.626
• >5	47(94%)	45(90%)	100(100%)	
5 min				
• <5	0(0%)	0(0%)	0(0%)	0.301
• >5	50(100%)	50(100%)	100(100%)	

Table 8: Mean Apgar score distribution of patients studied in two groups

Apgar score	Group A	Group B	P-value
1 min	7.94±0.24	7.76±0.43	0.011
5 min	9.00±0.00	8.80±0.40	0.001

The mean 1 min Apgar score in group A was 7.94±0.24 and in group B was 7.76±0.43.

The P-value 0.011 was statistically considerable. The mean Apgar score at 5 min in group A was 9.00±0.00 and in group B was 8.80±0.40. The P-value 0.001 was statistically significant.

DISCUSSION:

In the present study, the mean maternal age observed in Group A is 24.48 ± 2.83, while the mean maternal age seen in Group B is 24.92 ± 3.49. Majority of the pregnant women are aged between 21-30 years i.e., in Group A 90% pregnant women belong to the age group between 21-30 years, while in Group B 86% pregnant women are aged between 21-30 years of age. There is a small portion of teenage pregnancy comprising of 4% in Group A, 6% in Group B. 6% of pregnant women in Group

A and 8% pregnant women in group B are of age 31-40 years. In the study conducted by Kaur K et al.⁵, the mean maternal age is 24.41 ± 3.37 in Group A and 24.24 ± 3.17 in Group B. The average age of the mothers noted in the study by CE Pennell et al.⁶ is 27 ± 0.8 in two of the groups. The mean maternal age in this study was comparable with studies of Kaur K et al.⁵, Garg R et al.³ and Mathuriya G et al.⁷

In this study, the majority of the gravid women are primigravida. They constitute for 74 % in Group A and 70% in Group B. 27% of pregnant women are multigravida of which 12% belong to Group A and 15% belong to Group B. This data is similar to the study done by Shankarappa et al.⁸ The majority of the patients in most of the studies are Primi in both the groups. In the study conducted by Ajad J et al.⁹ equal proportions of primigravida and multigravida are noted in both the groups. In a study done by Mathuriya G et al.⁷, multigravida (86%) is relatively higher compared to primigravida (64%) in Group A.

The mean Maternal Gestational Age of the current study is 39 ± 3.14 in Group A & 39.4 ± 5.49 in Group B. Major portion of pregnant women in this group belong to gestational age 38-39 weeks. 40 % of pregnant women in Group A are beyond 40 weeks and 48% of pregnant women in Group B are beyond 40 weeks of period of gestation. Pregnant women with gestational age <38 weeks comprise 10% in Group A and 4% in Group B. The average gestational age in M Prager et al.¹⁰ is 40.3 in Group A and 40.2 in Group B. The mean period of gestation in the study done by Duc et al.¹¹ is 40.52 ± 0.8 in Group A and 40.60 ± 0.79 in Group B. The average period of gestation in the study done by Atad J et al.⁹ is 38 in Group A and 39 in Group B.

In the current study, the main indication for labour induction in Group A is Postdated pregnancy and Gestational HTN & Pre-eclampsia constituting 38% each of pregnant women. Pregnant women induced in view of Oligohydramnios in Group A is 10%. IUGR 4% and other indications comprise 10% pregnant women. In Group B, the main indication for Induction of labour is Postdated pregnancy i.e. 44%, next major indication is gestational HTN & pre-eclampsia comprising 30% of pregnant women. Pregnant women with Oligohydramnios are 8% in Group B, IUGR 6% and other indications are 12%. The indications in this study were comparable with that of the study done by Shankarappa et al.⁸ In the study done by Kaur K et al.⁵, the major indication for inducing labour in Group A is pre-eclampsia (40%) followed by postdated pregnancy (29%), whereas in Group B, pre-eclampsia is 32% and postdated pregnancy is 33%. Deshmukh et al.¹² (2011) found that 37 percent of cases were induced owing to GHTN and around 30 percent of cases were induced for post-dated pregnancy, with 5% each for IUGR. 5% of those in Group A and 0.5 percent of those in Group B were stimulated for oligohydromnios. In the CE Pennell et al trial⁶, 44 percent of women in Group A and 36 percent in Group B were induced for post-dates. In Group A, 22% were induced for GHTN, while in Group B, 26% were induced for GHTN. In Group A, GDM accounts for 9% of the total, whereas in Group B, it accounts for 4%. IUGR was found in 7% of Group A and 6% of Group B participants. Post dates (60 percent), GHTN (14.7 percent), and GDM (18.9 percent) were the three causes for labour induction in the study by Ajad J et al.⁹.

The present study has got an average Bishop's pre-induction score of 3.48 ± 0.908 in Group A and 3.38 ± 1.027 in Group B. This value is similar to the study done by Kaur K et al.⁵. In a study conducted by Kaur K et al.⁵, the mean Bishop's pre- induction score in Group A was 3.13 ± 0.87 and 3.36 ± 0.91 in Group B. The mean Pre induction Bishop score is 2.38 ± 0.56 in Group A and 2.5 ± 1.45 in Group B, according to Shankarappa VK et al's study⁸. Revathi et al.¹³ found that Group A had an average pre-induction Bishop score of 2.60 ± 1.55 and Group B had a mean pre-induction Bishop score of 2.86 ± 1.57 .

In this study, the mean post-induction Bishop score was 7.78 ± 1.474 in Group A and 7.4 ± 1.456 in Group B. Deshmukh et al.¹², Mathuriya et al.⁷, and Garg R et al.³ have all done similar research. In both groups, the majority of the patients seemed to have a Bishop's post-induction score of 6-10. Shankarappa et al.⁸ found that the mean post-induction Bishop score in Group A is 5.94 ± 1.80 and 5.94 ± 1.80 in Group B in their investigation. Garg R et al.³ found a mean post-induction bishop score of 7.16 ± 0.37 in Group A and 7.16 ± 0.37 in Group B in their investigation. The mean post-induction

Bishop score is 7.66 ± 1.74 in Group A and 8.34 ± 2.13 in Group B, according to Mathuriya et al⁷. Deshmukh et al¹² observed that the average Bishop's post- induction score in Group A is 7.04 ± 1.72 and 7.08 ± 1.87 in Group B in a study.

Fetal distress (10% in Group A and 16 % in Group B) and failed induction (four percent in Group A and ten percent in Group B) were the leading causes of LSCS in this study. In Group A, 4% of patients had LSCS due to non-progressing labour, while in Group B, 2% had LSCS due to non-progressing labour. Emergency LSCS was performed on a limited percentage of pregnant women who had Meconium-Stained Liquor, namely 2% in Group A and 8% in Group B. These findings are comparable to those of Shankarappa VK et al⁸ and Garg R et al³ studies. In the study done by Kaur K et al⁵, the major indication for LSCS in two of the groups is Fetal distress comprising 40% of the gravid women in each group. In the majority of the studies, Fetal distress is the main indication for LSCS in both the groups.

The present study had a mean induction delivery interval of 13.82 ± 4.984 in Group A and 15.3 ± 4.781 in Group B. These values are similar to the studies conducted by Kaur K et al⁴³ and Deshmukh et al¹². The study done by Shankarappa VK et al⁸ had a mean induction delivery interval of 28.01 ± 12.14 in Group A and 13.56 ± 7.1 in Group B. There was no much difference noted in the induction delivery interval in the study conducted by Alam et al¹⁴ and Kaur K et al⁵ between both the groups. The major difference in induction delivery interval was noted in the study done by Shankarappa et al⁸ showing a relatively longer interval of about 28hrs in Group A.

In the current study, the mean APGAR score within 1 minute was 6.92 ± 1.16 in Group A and 6.8 ± 1.29 in Group B. Within 5 minutes, Group A's mean APGAR score is 8.76 ± 0.56 , whereas Group B's is 8.64 ± 0.60 . The findings were comparable to those of Shankarappa VK et al⁸ study. Shankarappa VK et al⁸ found that the mean APGAR within 1 minute in Group A is 7.65 ± 0.81 and 7.62 ± 0.68 in Group B. Within 5 minutes, Group A's mean APGAR is 8.81 ± 0.79 , whereas Group B's is 9.44 ± 0.13 .

CONCLUSION:

Accomplishing a successful vaginal delivery in women with an unfavorable cervix presents an obstetric challenge. The introduction of various mechanical and pharmacological methods for inducing labor has led to an increase in the percentage of successful vaginal births. The intracervical Foley's catheter and intracervical PGE2 gel are both safe options for inducing labor at term. When compared to the use of PGE2 gel alone, the combination of Foley's catheter and PGE2 gel results in improved outcomes, including a higher post-induction Bishop score, a shorter interval from induction to delivery, a reduced number of PGE2 gel doses, and a lower requirement for labor augmentation. There is no significant difference in fetal outcomes depending on the method used for induction.

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