

Comparative study of Foley's catheter and prostaglandin E2 gel for pre-induction cervical ripening



Shruti J Shetty¹, Spandana JC², Anju Arpana³, Chaitra Sathyanarayana⁴

¹Senior Resident, ^{2,4}Assistant Professor, ³Associate Professor, Department of Obstetrics and Gynaecology BGS Global Institute of Medical Sciences, Bengaluru, Karnataka, India

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ABSTRACT

Background: Induction of labor is a crucial and customary clinical procedure in obstetrics. It is arguably one of the most abused procedures. Cervical ripening determines the success of delivery. The availability of newer oxytocics and induction techniques which are simpler and also more predictable has significantly modified our traditionally conservative attitude toward induction of labor. **Aims and Objectives:** The objective of this study was to determine the effectiveness of Foleys catheter against prostaglandin E2 (PGE2) gel for pre-induction cervical ripening. **Materials and Methods:** Women attending hospital for induction of labor, with a Bishop's score <6, were allocated randomly to Foley's group (Group F) and PGE2 gel group (Group P). Fifty women were allocated to Foley's group (Group F) and 50 were allocated to gel group (Group P). The Foley's group had a number 18 Foley catheter inserted into cervix, bulb inflated and placed on traction. Further augmentation was done, after Foleys extrusion or 6 h after gel, either with PGE2 gel or oxytocin solution depending on Bishops score. **Results:** The Foley's group had significantly higher change in Bishop's score (3.12 vs. 2.66, P=0.04). The Foleys group required lesser number of further doses of gel as compared to gel group. No differences were found between the two groups with respect to induction to delivery interval, mode of delivery, non-reassuring fetal heart rate patterns, or baby weight. **Conclusion:** Foleys catheter was associated with greater change in Bishops score as compared to intracervical PGE2 gel. It was not associated with any side effect during induction process.

Key words: Foley's catheter; Induction of labour; Prostaglandin E2 gel

INTRODUCTION

Induction of labor is the use of mechanical or pharmacologic means to stimulate regular uterine contractions before the commencement of labor, resulting in progressive cervical dilatation and subsequent delivery.¹ The emergence of newer, more effective, and more predictable oxytocics and induction procedures has drastically altered our previously conservative stance regarding induction of labor. Cervical ripening and induction of labor are aimed at achieving the vaginal birth rather than resorting to cesarean section.¹ Pre-induction cervical Bishops score determines the success of induction.²

The correlation between the presence of a favorable cervix and subsequent vaginal delivery was first described by Bishop. The presence of a ripened cervix correlated closely with successful induction of labor.³ The methods for cervical ripening, that are safe to both the mother and fetus, cause minimal discomfort to mother, not requiring extensive monitoring, with low cost is the ideal.⁴ These include (a) stripping the membranes, (b) intravaginal or intracervical application of prostaglandins (PGs), (c) intracervical placement of osmotic dilators, (d) oxytocin, and (e) amniotomy.⁵ Krause in 1853 first described the use of the Foley's catheter for the induction of labor.⁶ In 1967, Embrey and Mollison found a success rate of 94% with use of Foleys catheter for cervical ripening in 100 women.⁷

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Address for Correspondence:

Dr. Anju Arpana, Associate Professor, BGS Global Institute of Medical Sciences, Bengaluru, Karnataka, India. **Mobile:** +91-8088352525.

E-mail: meetyourdoctor01@gmail.com

Mechanical or pharmacological ripening is required for women with an unfavorable cervix. The mechanical methods of cervical ripening cause stretching and dilatation of lower uterine segment and cervix. Use of extra-amniotic balloon catheter for cervical ripening has the advantages of reversibility, lack of side effects, low cost, and simplicity.⁸ PGE₂ gel has been approved by the Food and Drug Administration for cervical ripening and induction of labor for more than a decade.

The Foley's catheter and intracervical dinoprostone PGE₂ gel are compared for safety and efficacy for induction of labor in this study.

Aims and objectives

The objective of the study was to compare the efficacy of foley's catheter and intracervical PGE₂ gel for improving preinduction cervical ripening.

MATERIALS AND METHODS

This is a prospective comparative clinical study conducted in the department of OBGY at St Philomena's Hospital, Bangalore, from January 2012 to October 2012. A total of 100 patients fulfilling the inclusion criteria were enrolled in this study. They were randomly distributed into two groups after a written informed consent.

Inclusion criteria

The following criteria were included in the study:

- Term gestation (>37 weeks) with cervix not favorable. (Bishop's score <6)
- Singleton pregnancy
- Cephalic presentation
- Intact membranes.

Indications for induction

- Elective induction at 40 weeks
- Prolonged pregnancy
- Pregnancy induced hypertension
- Gestational diabetes
- Oligohydramnios
- Intrauterine growth restriction
- Rh isoimmunization.

Exclusion criteria

The following criteria were excluded from the study:

- Presence of cervicovaginal infection
- Rupture of membranes
- Low lying placenta
- Previous uterine scar
- Multiple pregnancy
- Antepartum hemorrhage
- Intrauterine fetal death
- Hypersensitivity to PGs.

The patients were randomly assigned to either Foley catheter group (n=50) and PGE₂ gel group (n=50). History was taken in detail and clinical examination done. Bishop's score determined. NST taken for 20 min before beginning induction.

Foley's group (Group F)

- After ensuring empty bladder, pt placed in dorsal position
- Under aseptic precaution No. 18, Foley's catheter was inserted into the endocervical canal using artery forceps and then bulb inflated with 60 ml distilled water
- Moderate traction applied to catheter by taping it to the inner aspect of woman's thigh
- Cardiotocography (CTG) taken after 1 h
- Pt allowed to ambulate with fetal heart rate (FHR) monitoring every hour until onset of painful contractions
- Bishop's score determined once Foley's bulb expelled or after 12 h
- PGE₂ gel instilled if Bishop's score <8 or oxytocin augmentation done if score >8 as per obstetrician's convenience.

PGE₂ gel group (Group P)

About 0.5 mg PGE₂ gel instilled into endocervical canal under all aseptic precautions. CTG taken after 1 h and then allowed to ambulate with hourly FHR monitoring or until painful uterine contractions ensued. Bishop's score determined after 6 h. Repeat PGE₂ gel instillation done if Bishop's score <8 with no contractions to a maximum of three doses in 24 h.

In both the groups, there was no change in the active management of labor.

Outcome measures include

- Change of Bishop's score
- Number of further doses of PGE₂ gel required in both the groups
- Induction-delivery interval
- Mode of delivery
- Indication for lower segment cesarean section (LSCS)
- Neonatal intensive care unit (NICU) admission.

Statistical methods

Descriptive statistics were reported using mean±standard deviation for the continuous variable, numbers, and percentage for the categorical variable.

Chi-square test or Fisher's exact test was done to test the association between the method of induction and Foley's and PGE₂ gel group, with demographical and clinical variables.

Independent t-test was done to compare the two groups for the continuous variable. Analysis was done and $P < 0.05$ was considered as significant.

RESULTS

In the present study, 100 patients were included and randomly assigned to two groups. Following results were obtained. The majority of patients were between the age of 22–26 years with mean age of 25.10 ± 4.59 and 25.50 ± 3.27 in the Group F and Group P, respectively.

Mean gestational age was 39.72 ± 0.93 and 39.05 ± 1.16 in Group F and Group P, respectively. There was no significant difference in age distribution and gestational age of patients assigned between two groups.

There was no significant difference in parity of patients in two groups. The most common indication for induction of labor was elective induction “as shown in Table 1.”

“As shown in Table 2,” the mean of pre-induction Bishop’s score between women allotted into the two groups was almost the same. There was no significant difference in pre induction and post induction bishops score between the two groups. When post-induction Bishop’s score was compared to pre-induction Bishop’s score for each method individually, the improvement was found to be statistically significant with $P < 0.001$. Hence, each method was effective for pre-induction cervical ripening.

However, the mean change in Bishop’s score was significantly greater in Foley’s group compared to PGE₂ gel group with $P = 0.04$ (< 0.05) “as shown in Table 3.”

The number of further doses of PGE₂ gel required was significantly lower in Foley’s group than PGE₂ gel group with $P = 0.004$. About 40% of women did not require further dose of PGE₂ in Foleys group whereas 52% of women did not require it in gel group. About 6% of women required two doses of PGE₂ gel in Foleys group whereas 26% women in gel group required two doses of PGE₂ gel.

The average number of gels required for delivery was less in Foley’s group “as shown in Table 4.”

There was no significant difference in mode of delivery in two groups with $P = 0.688$. The mean induction to delivery interval was 15.65 ± 5.65 h in Foley’s group and 15.66 ± 6.62 h in dinoprostone gel group. The difference was not statistically significant. ($P = 0.991$) “as shown in Chart 1.”

The most common indication for LSCS was failure to progress in Foley’s group whereas failed induction in gel group. About 26% of women delivered in < 12 h in Foleys group and 4% of women required > 24 h whereas 34% of women delivered in < 12 h and 12 % required > 24 h in dinoprostone gel group “Chart 2.”

When side effects such as GI effects or tachysystole were compared, there was no such S/E in Foley’s group “as shown in Table 5.”

There was no significant difference in postpartum fever between the two groups. There was no statistically significant difference in fetal outcome in terms of birth NICU admission.

DISCUSSION

This study compared intracervical Foley’s catheter with PGE₂ gel for pre-induction cervical ripening. In our study, both the groups were comparable in terms of mean age, gestational age, parity, and indication for induction.

The mean pre-induction Bishop’s score was 2.82 ± 1.44 and 2.88 ± 1.58 in Foley’s and PGE₂ gel group, respectively, with $P = 0.84$ meaning groups were matching to start with. The mean post-induction score was 5.94 ± 1.58 and 5.54 ± 2.04 in Foley’s and PGE₂ gel group. When improvement in post-induction score was considered for each group independently, it was found to be statistically significant with $P < 0.001$. The results are comparable to study Sciscione et al.,⁹ where the mean of post-induction score in Foley’s group was 6.5 ± 1.63 and in PGE₂ gel group was

Table 1: Indication for induction

Indication for induction	Foley’s group		PGE ₂ gel group	
	Number	Percentage	Number	Percentage
Elective Induction	27	54	24	48
PIH	10	20	18	36
GDM	4	8	3	6
Oligohydramnios	7	14	0	0
IUGR	2	4	5	10
Total	50		50	

PGE₂: Prostaglandin E₂, PIH: Pregnancy-induced hypertension, GDM: Gestational diabetes mellitus, IUGR: Intrauterine growth restriction

5.1±1.23 with P<0.001. Hence, each method was effective for pre-induction cervical ripening.

The mean change of score was 3.12±1.02 and 2.66±1.22 in our study which correlated with study by Sciscione et al.,⁹ and St Onge et al.²

Another study by Suri et al.,¹⁰ showed mean change of Bishop's score 5.32±1.47 and 2.64±0.93 in the Foley's and PGE2 group. However, the mean change of Bishop's score was significantly greater in Foley's group compared with gel group with P=0.04.

When the change in Bishop's score was compared between two groups, we got P=0.04, indicating improvement was better with Foley's when compared to gel group. In our

study, we used gel for further ripening in Foley's group if Bishops <6, after Foley's expulsion or removal. When the number of further doses required was compared, it was less for Foley's group. This was not done in other studies. Hence, our study could not be compared to other studies in this parameter.

Our study findings demonstrate no significant difference in mode of delivery in both groups. The risk of tachysystole was higher in PGE2 gel group as compared to Foley's group.

Other studies done later than our study also showed similar results. The meta-analysis comprising 96 RCTs with a total of 17,387 women had lowest rate of uterine hyperstimulation with FHR alterations were associated with the use of a Foley catheter to induce labor.¹¹

Another analysis analyzing data from eight studies, including 1191 women who received the intracervical Foley catheter balloon, and 1199 women who received the dinoprostone insert showed no significant difference between the two groups in terms of the induction-to-delivery interval. In terms of cesarean delivery, Apgar score, or side effects such as maternal infection, postpartum hemorrhage, and hyperstimulation, there was no significant difference between the two approaches.¹²

Another study, with total 825 pregnant women with cephalic presentation and an unfavorable cervix were randomly assigned to the double-balloon or vaginal dinoprostone (3 mg) groups during induction, showed that balloon group had a considerably higher failure rate for labor induction. The rates of cesarean sections and newborn outcomes were comparable. Overall, the two induction strategies were equal in terms of efficacy and safety.¹³

The use of a controlled-release dinoprostone insert to induce labor appears to be more effective than using a Foley catheter. The former strategy, on the other hand, results in more frequent uterine contractions.¹⁴

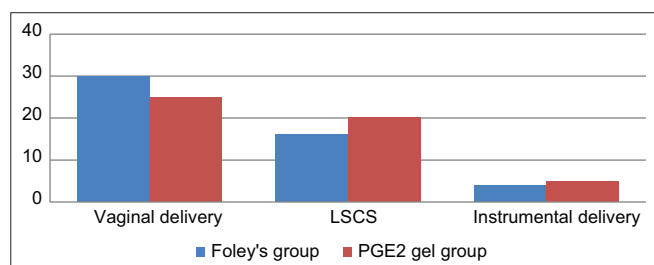


Chart 1: Mode of Delivery

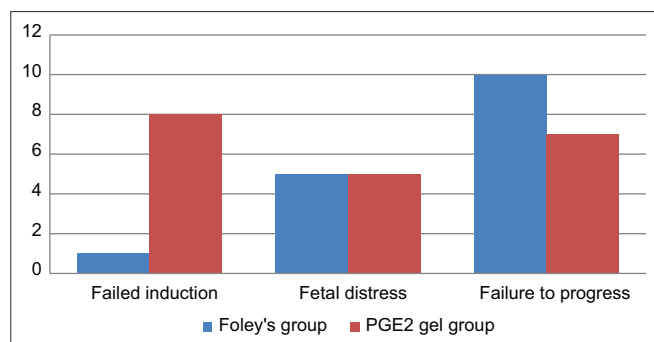


Chart 2: Indication for LSCS

Groups	Pre-induction Bishop's score	Post-induction Bishop's score	P-value
Group F	2.88±1.44	5.94±1.58	<0.001
Group P	2.88±1.45	5.54±2.04	<0.001

Change in bishop's score	Group F (%)	Group P (%)	P-value
0-2	15 (30)	23 (46)	
3-5	35 (70)	27 (54)	
Total	50	50	
Mean	3.12±1.02	2.66±1.22	0.04

Number of further doses of PGE2 gel required	Group F (%)	Group P (%)	P-value
0	20 (40)	26 (52)	0.004
1	27 (54)	11 (22)	
2	3 (6)	13 (26)	
Total	50	50	

PGE2: Prostaglandin E2

Side effects	Group F	Group P
G/I effects	0	12 (24)
Tachysystole	0	8 (16)

In a study conducted on 300 women, both methods yielded similar results for vaginal delivery within 24 h and cesarean section rates.¹⁵

In a study, the results suggest that Foley ambulatory catalog and PGE2CR are equivalent from insertion to delivery. However, PGE2 inserts are associated with higher tachycardia contractility and the need for a second CR method.¹⁶

In multiparous women who require cervical maturation, all cervical maturation methods have similar success rates. However, the use of PGE2CR inserts is associated with significantly longer delivery intervals compared to Foley catheters or PGE2 gels.¹⁷

Postpartum fever was seen in 14% women in Foley's group and 2% women in gel group. The C-reactive protein was negative in all cases and they did not need any further hospital stay due to fever. Febrile morbidity was noted in by James et al.,¹⁸ in <10% of patients.

Tachysystole was seen in 16% women in gel group. There were no cases with FHR abnormality, needing tocolytic therapy. Uterine hypercontractility was observed in 15% of cases by Ekman et al.¹⁹

Limitations of the study

Number of women included in the study was less.

Induction of labour following cervical ripening was done as per obstetrician's convenience. Hence difficult to compare and interpret induction to delivery interval.

Delivery expense for the two agents were not compared.

CONCLUSION

Pre-induction cervical ripening is a major obstetric challenge because achievement of a vaginal delivery is the greatest factor determining the ability to successfully induce labor in a woman who requires labor induction.

The results of this study confirm that when compared to PGE2 gel Foley's catheter is an equally effective method for pre-induction cervical ripening, for improvement of cervical score, success of induction, and the induction delivery interval. The Foley's catheter was equally acceptable to the patients as PGE2 gel. Foleys catheter is an effective method of induction in developing countries when cost and storage issues were considered. Prophylactic antibiotics can be used to prevent infection which can be an important but preventable issue with mechanical method. Hence, it can be considered as safe option to PGE2 gel for initial ripening of cervix in women with poor Bishop's score.

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Authors' Contributions:

SS- Contributed to the concept and design of study, acquisition of data, analysis and interpretation of data. The first draft of manuscript was written by **SS** and **SJ**.
AA and **CS-** Revised the study critically for important intellectual content. All authors read and approved the final manuscript.

Work attributed to:

BGS Global Institute of Medical Sciences, Bangalore

ORCID ID:

Dr. Shruti J Shetty - <https://orcid.org/0000-0002-9069-9227>

Dr. Spandana JC - <https://orcid.org/0000-0002-9829-980X>

Dr. Anju Arpana - <https://orcid.org/0000-0001-9420-8424>

Dr. Chaitra Sathyanarayana - <https://orcid.org/0000-0003-3393-7222>

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