

DOI: <http://dx.doi.org/10.18203/2320-1770.ijrcog20162637>

Research Article

A comparative study of intra-cervical foley's catheter and PGE2 gel for pre-induction cervical ripening

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Received: 03 June 2016

Accepted: 01 July 2016

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ABSTRACT

Background: Cervical ripening, before induction of labour, is needed to increase the success of labour induction, to reduce complications and to diminish the rate of cesarean section and duration of labour. Pharmacological preparations are in widespread use for cervical ripening but are not free from side-effects and complications. Mechanical methods, i.e. the use of Foley's catheter balloon, though effective have not gained much popularity because of the fear of infection. Therefore, this study has been conducted to prove the efficacy and safety of extra amniotic Foley catheter balloon and to compare it with intra-cervical prostaglandin E2 (PGE2) gel. The objective of this study was to the success of induction of labor depends on the cervical status at the time of induction. For effective cervical ripening both Foley's catheter and PGE2 gel are used. The aim of this study was to compare the efficacy of intra cervical Foley's catheter and intra cervical PGE2 gel in cervical ripening for the successful induction of labor.

Methods: A randomized, comparative study was conducted in the department of obstetrics and gynaecology, Assam Medical College and Hospita, Dibrugarh, during a period of one year from July 2014 to June 2015. 200 patients at term with a Bishop's score ≤ 3 with various indications for induction were randomly allocated to receive (100 pts) intra-cervical Foley's catheter or PGE2 gel (100 pts). After 6 hours post induction, Bishop's score was noted, labor was augmented if required. Statistical analysis was done using Chi square test and t test.

Results: The groups were comparable with respect to maternal age, gestation age, indication of induction and initial Bishop's score. Both the groups showed significant change in the Bishop's score, 5.10 ± 1.55 and 5.14 ± 1.60 for Foley's catheter and PGE2 gel, respectively, $P < 0.001$; However there was no significant difference between the two groups. There was no significant difference in the side effects and caesarean section rate in both groups. The induction to delivery interval was 16.01 ± 5.50 h in group F and 16.85 ± 3.81 h in group P ($p = 0.073$). Apgar scores, birth weights and NICU admissions showed no significant difference between the two groups.

Conclusions: This study shows that both Foley's catheter and PGE2 gel are equally effective in pre induction cervical ripening.

Keywords: Cervical ripening, PGE2, Foley's catheter, Induction of labor

INTRODUCTION

Cervical ripening refers to a process of preparing the cervix for induction of labor by promoting effacement and dilatation as measured by Bishop's score.¹ Induction of labour should be safe, simple and effective. The success of induction depends upon the consistency, compliance and configuration of cervix.² With low Bishops score, there may be increased rate of caesarean

section delivery, maternal fever and fetal hypoxia.^{3,4} Therefore a simple and effective method for pre-induction cervical ripening is of use.

Ripening of cervix may be achieved by mechanical techniques such as introduction of trans-cervical Foleys catheter.^{5,6} It can cause mechanical dilatation of cervix and stimulates endogenous release of prostaglandins by stripping the fetal membranes and release of lysosomes

from decidual cells.^{7,8} Use of catheter is associated with reduced induction delivery interval, decrease caesarean section rate, increase rate of spontaneous vaginal delivery.⁹ Chances of infection are no more than that of the usual hospital rate if strict aseptic precautions are observed.¹⁰

Intra-cervical application of PGE2 gel is also found to be effective for ripening of cervix as it can have a combined contraction inducing and cervical ripening effect.¹¹ It is in use since 1960s for cervical ripening. Local application of PGE2 causes direct softening of cervix by a number of different mechanisms. It can cause connective tissue softening, cervical effacement and uterine activity.^{12,13} PGE2 gel can be used in cases of heart disease, PIH and eclampsia also.¹⁴

The purpose of this study was to compare the efficacy of intra-cervical Foley's catheter with PGE2 gel for pre-induction cervical ripening. The induction delivery interval, maternal and fetal outcomes and the need for augmentation of labor in these two groups were also compared.

METHODS

The present study was carried out in the department of obstetrics and gynaecology, Dibrugarh, for a period of one year extending from July 2014 to June 2015. It was approved by ethical committee of the institution. All the cases fulfilling the inclusion and exclusion criteria and willingness to participate in the study were included in the study and they were divided into two groups. There were total 200 cases

Inclusion criteria

- Primigravida
- ≥ 37 weeks of gestation
- Singleton pregnancy
- Cephalic presentation
- Bishop's score ≤ 3
- Intact membranes
- Cases where conditions were fulfilled for vaginal delivery

Exclusion criteria

- Multiple pregnancy
- Malpresentation
- Absent membrane
- Antepartum haemorrhage
- Previous uterine scar
- Medical diseases, e.g. heart disease, renal disease, etc.

The patients were randomly allocated to either Foley's catheter (group F) or PGE2 gel (group P) method. The Bishop's score was determined earlier. Each patient was questioned in detail and examined thoroughly. Last

menstrual period was ascertained and correlated clinically.

Primary outcome

Post induction Bishop's score was assessed after 6 hours of induction preferably by the same person.

Secondary outcome

- Demographic profile, gestation age, improvement of Bishop's score, induction-delivery interval, mode of delivery and feto-maternal outcome were noted.
- Dose repetition of PGE2 gel was considered if post-induction Bishop's score become ≤ 6 in both the groups.
- Need of augmentation of labor was assessed and implemented by other methods such as artificial rupture of membrane (ARM) and/or oxytocin administration.
- Failure of induction was declared if patient failed to go in active phase of labor within 48 hours of induction.

Foley's catheter

An 18 size Foley's catheter (it comes in pre-sterilized pack using ethylene oxide) was introduced through cervix to extra-amniotic space using a sterile technique with the aid of a speculum and sponge holding forceps and 30 ml distilled water was instilled into the balloon. Then balloon is pulled up to the internal os. Catheter was tapped with thigh. Prophylactic antibiotic was given

Prostaglandin gel

PGE2 gel is available in the name of cerviprime gel as a sterile preparation containing 0.5 mg of dinoprostone per 3 gm (2.5 ml) of gel in a prefilled syringe with a catheter for endocervical application. After exposing the cervix by speculum 0.5 mg of PGE2 was inserted intra-cervically from a loaded syringe and the patients were kept in lying down position at least 30 minutes for absorption of drugs.

Statistical methods

Student's t test and Chi square test was used to statistically compare the two groups. Differences with a p value of <0.05 was considered statistically significant with the confidence limit of 95%.

RESULTS

Group F and Group P had 100 randomized patients each. Both the groups were comparable with respect to the maternal age, gestational age, indication for induction and pre-induction Bishop's score.

No statistically significant difference was demonstrated between the two groups.

In this present study improvement in the Bishop's score in Group F was 5.10 ± 1.55 (mean \pm SD, $p < 0.001$) and in Group P it was 5.14 ± 1.60 (mean \pm SD, $p < 0.001$);

however no significant difference in the mean changes in the two groups could be established.

Table 1: Demographic profile.

Variables	Group F	Group P	P value
Maternal age	22.59±3.38	22.32±3	0.55
Gestational age	38.48±1.35	38.43±1.29	0.78
Indication for induction			
PIH	40 (40%)	37 (37%)	
Postdatism	32 (32%)	30 (30%)	
IUGR	6 (6%)	7 (7%)	
Oligohydromnio	3 (3%)	4 (4%)	
IUFD	6 (6%)	7 (7%)	
others	13 (13%)	15 (15%)	
Mean pre-induction score	1.91±0.7	1.90±0.77	0.92

Table 2: Change in Bishop score.

Bishop's score	Group-F (Mean±SD)	Group-P (Mean±SD)	p value
Mean pre-induction score	1.91±0.70	1.90±0.77	0.92
Mean post-induction score	7.10±1.49	7.04±1.60	0.78
Mean change in score	5.10±1.55	5.14±1.60	0.97
t = 31.04 p<0.0001; t = p<0.0001			

The need for further augmentation of labor was studied in this study (Table 3). Spontaneous labor ensued in 23 patients in Group F (23%) compared with 27 patients in Group P (27%). In Foley's catheter group, need for augmentation of labor was required by doing ARM (n = 8) oxytocin infusion (n = 39) and both ARM + oxytocin 30(30%) patients required. In PGE2 gel group, 11 patients required ARM, 38 patients required oxytocin and 24 patients required both ARM + oxytocin. There was no significant difference in need for augmentation in both groups.

Table 3: Need for augmentation.

Mode of delivery	Group F	Group P	P value
None	23 (23%)	27 (27%)	0.62
ARM	8 (8%)	11 (11%)	0.62
Oxytocin	39 (39%)	38 (38%)	0.88
ARM+oxytocin	30 (30%)	24 (24%)	0.42
Total	100	100	

No significant difference in need for augmentation in both groups.

Table 4 shows no significant statistical difference in spontaneous vaginal delivery in both the groups. Group F had 76% (n = 76) spontaneous deliveries whereas group P had 77% (n = 77) spontaneous deliveries.

Table 4: Mode of delivery and induction-delivery interval.

variable	Group F	Group P	P value
Spontaneous	76	77	
Instrumental	3	4	0.88
LSCS	21	19	
Total	100	100	
Induction-delivery interval	16.01±5.50	16.85±3.81	0.073

The need for operative intervention (LSCS) was also not significant in both the groups. LSCS was done for fetal distress in group F for 9 cases and in group P for 11 cases. The other indications for LSCS being failure to progress (6 and 5 respectively and failure of induction (3 and 1 respectively).

Table 5 shows the incidence of perinatal asphyxia with Apgar score ≤7 at 5 minutes and me conium aspiration syndromes were similar in both the groups. The neonatal birth weights were also comparable in both the groups (2.57±0.44 in group F and 2.58±0.48 in group P). 20% of babies in group F (n = 20) and 18% of babies in group B (n = 18) got admitted in NICU. However the morbidity in both the groups was not statistically significant.

Table 5: Neonatal outcome.

variable	Group F	Group P	P value
MAS	4	4	1
LSCS for FD	9	11	0.81
1 minutes APGOR <7	13	12	0.83
5 minutes APGOR <7	7	8	0.78
NICU admission	20	18	0.85
Neonatal deaths	3	4	1

DISCUSSION

The results of this study confirm that both Foley's catheter and PGE2 gel are equally effective in pre-induction cervical ripening. The mean change in Bishops score in Foleys catheter 5.10±1.55 (p<0.0001) and PGE2 gel 5.14±1.60 (p<0.0001) were highly significant. However, a comparison between the groups revealed that one method did not confer a statistically significant advantage over the other. There have been theoretic concerns regarding the introduction of infection with the use of Foley's catheter. In this study there was no infectious morbidity. Similar were the observation of St. Onge and Connors, Jozwiak M and Anthony C et al.^{4,15,16}

The need for oxytocin induced augmentation of labor was 39% in Group F and 38% in group P. This is in agreement with studies done by Dewan et al. and Hertelendy F et al.^{17,18}

The induction delivery interval showed no significant difference in the two groups. The mean I-D interval was 16.01±5.5 h in Foley's group and 16.85±3.81 h in PGE2 group. Similar observations were observed by Dewan et al, Pennel C et al.^{17,19}

The rate of LSCS in Group F was 21% and 19% in Group P (p = 0.88). The most common indication for LSCS in Group F was fetal distress. Group F had 9 cases for FD and Group P had 11 cases of FD. The rate of LSCS in our study is agreeable.^{16,19} There was no association of increased rate of cesarean section with the Foley's catheter PGE2 gel use.

Fetal outcome data showed no significant difference between Group F and Group P with respect to birth wt (2.57±0.44 and 2.58±0.48), MAS (4 and 4 respectively), 1 min Apgar score <7 (13 and 12 respectively), NICU admission rate (20 and 18 respectively). Thus the present study shows that the fetal outcome results were also comparable in both the groups.

The total cost of Foley's catheter was much less than PGE2.¹⁷

CONCLUSION

In conclusion this study has shown that for pre-induction cervical ripening there is no difference in efficacy between intra cervical PGE2 gel and intra cervical Foley's catheter. Also, other factors like induction delivery interval maternal and neonatal outcome and need for oxytocin for further augmentation were similar in both the groups. Both methods are complementary to each other.

Funding: No funding sources

Conflict of interest: None declared

Ethical approval: The study was approved by the Institutional Ethics Committee

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Cite this article as: Alam A, Ahmed EA. A comparative study of intra-cervical foley's catheter and PGE2 gel for pre-induction cervical ripening. *Int J Reprod Contracept Obstet Gynecol* 2016;5:2644-7.