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Original Research Article

Induction of labor in women with unfavourable cervix: comparison of efficacy of intracervical Foley catheter with PGE2 gel

Shilpa Gupta*, Bhumika Kagathray

Department of Obstetrics and Gynecology, GMERS Medical College, Sola, Ahmedabad, Gujarat, India

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***Correspondence:**

Dr. Shilpa Gupta,

E-mail: shilp7anup@yahoo.co.in

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ABSTRACT

Background: The aim of our study was to compare the efficacy, safety and patient's satisfaction of intracervical Foley catheter with intracervical dinoprostone gel (PGE2 gel) for cervical ripening for successful induction of labor.

Methods: Prospective study was conducted in Department of Obstetrics and Gynaecology, M P Shah Medical College, Jamnagar, Gujarat. 317 women with term pregnancy with bishop score of less than 4 with various indications for induction were included. Intracervical foley catheter was kept in 162 women for cervical ripening (group A) while intracervical PGE2 gel was kept in rest 155 women (group B). The change in the bishop score, progress of labor, adverse effects and outcome of labor along with the patient's satisfaction were assessed.

Results: With regard to the obstetrical parameters, the two groups were comparable with respect to maternal age, gestational age, parity, indication for induction and initial bishop score. At 12 hours, both the groups showed significant improvement in bishop score, 5.2 ± 1.81 and 4.8 ± 1.76 in Foley catheter and PGE2 gel respectively. Mean induction to delivery interval was 18.8 ± 5.5 in group A and 17.9 ± 5.3 in group B, which was statistically insignificant. No significant differences in side effects, mode of delivery and APGAR score were noted in both the groups. However, the incidence of hyperstimulation and tachysystole was higher in PGE2 gel group.

Conclusions: This study shows that both Foley catheter and dinoprostone gel appear to be equally effective agents for cervical ripening. Intra-cervical foley catheter is cheap, causes less fetal distress and is safer than PGE2 gel.

Keywords: Bishop score, Dinoprostone gel, Induction of labour, Intracervical foley catheter

INTRODUCTION

Induction of labor is one of the commonest obstetric intervention in our day to day practice due to various indications, occurring in up to 30% of pregnancies.¹ The success of induction depends upon the initial status of cervix and the most favorable outcome occurs if the cervix is soft and effaced, which is assessed by bishop score.² Thus, the unripe cervix is well known impediment for the successful induction of labor.³

Since age, many methods have been devised to ripen the cervix both cervical and mechanical. Pharmacological

agents, most commonly, PGE2 gel has been widely used and studied. Local application of PGE2 gel results in direct softening of cervix by a number of different mechanisms.^{4,5} However, in 1 to 5% women, uterine tachysystole and fetal distress have been observed.⁶

Mechanical methods like intracervical foley catheter are also an equally effective method for cervical ripening. Its mechanical action strips the fetal membrane from lower uterine segment and causes release of prostaglandins. Thereby consistency and effacement of the cervix is improved. The superiority of these methods over dinoprostone gel includes relatively low cost, easy

insertion, simplicity of preservation and few adverse effects.

The present study was undertaken to evaluate the efficacy, safety and patients satisfaction of intracervical Foley catheter in comparison to intracervical PGE2 gel in induction of labor.

METHODS

This prospective study was conducted in department of Obstetrics and Gynecology, M. P. Shah Medical College, Jamnagar. In the study period from November 2013 to January 2015, 317 pregnant women at term with various indications for induction of labor after undergoing vaginal examination to determine the bishop score were included in the study after written valid consent.

Inclusion criteria

- Primigravida
- >37 weeks of gestation
- Singleton pregnancy
- Cephalic presentation
- Bishop score <4
- Intact membrane.

Exclusion criteria

- Multiple pregnancy
- Malpresentation
- Absent membrane
- Previous LSCS
- Medical conditions i.e. heart disease, diabetes and hypothyroidism
- APH.

Intracervical Foley catheter was used as method of induction in 166 women (group A), while intracervical PGE2 gel was used in rest 155 women (group B).

After admission to labor room, a detailed history, physical and obstetric examination including per vaginal examination for assessment of bishop score were done. All necessary investigations as per hospital protocol were carried out. In group A patients, taking all aseptic precautions, Foley catheter no. 24F was inserted above the internal os and inflated with 80 ml normal saline and then pulled back. So that the bulb rests on internal os. The catheter was strapped to the inner aspect of one leg with moderate tension. It was removed after 12 hours, if till then spontaneous expulsion had not occurred. In control group, dinoprostone gel 0.5 mg in 3 gm gel was introduced in the endocervical canal and posterior fornix of vagina. The dose was repeated after 6 hours if there was no improvement in the bishop score. Oxytocin augmentation was started if bishop score >7. Each subject had sterile vaginal examination 4 hourly or earlier when

clinically indicated. Serial assessment was preferably made by the same individual whenever possible. In our study, failed induction was defined as women with no improvement in the bishop score even after 12 hours.

The primary outcome was change in bishop score. The secondary outcome were induction to delivery interval, need for oxytocin augmentation, intrapartum complications, mode of delivery and maternal and neonatal outcome. After the completion of procedure, women were given satisfaction questionnaires, which assessed the overall satisfaction with the procedure and the pain on insertion of Foley catheter or PGE2 gel and during cervical ripening.

Statistical analysis

Statistical analysis was done by chi square test. Differences with a p value <0.05 were considered statistically significant with confidence limit of 95%. Data was analyzed with SPSS software version 20.

RESULTS

A total of 317 patients were enrolled for study of which 162 patients were selected for intracervical foley catheter (group A) and 155 women were given intracervical dinoprostone gel (group B). All patients were primigravida. Both groups were comparable with respect to the demographic parameters of maternal age, gestational age, indication of induction and pre induction bishop score. The most common cause for pregnancy termination was post-datism followed by hypertensive disorders in both the groups.

Table 2 shows the mean change in bishop score after 12 hours of initiation of induction. In both the groups, there was considerable improvement. The mean change in bishop score was 5.2 ± 1.81 in group A and in group B it was 4.9 ± 1.76 . Thus no significant difference in mean change in both groups was established. In group B, out of 155 women, 64 (41.3%) women needed a second dose of PGE2 gel, while in group B no Foley catheter was needed to be replaced after the initial insertion.

Table 3 shows the intrapartum events. Oxytocin augmentation was started when bishop score was > 7 and adequate uterine contraction was not occurring. Oxytocin augmentation was needed in 55.5% women in group A compared to 47.7% in group B. The discrepancy might be due to the second dose of PGE2 gel inserted in group B patients. The incidence of abnormal fetal heart rate was higher in group B. 33 patients had hyperstimulations which was treated by disconnecting oxytocin drip. The incidence of tachysystole was more in group B (22.5%). The mean interval from start of induction to labor end point of vaginal delivery was comparable in both groups (18.8 ± 5.5 hours in group A and 17.9 ± 5.3 hours in group B).

Table 1: Demographic profile.

Variable	Group A (n= 162)	Group B (n=155)	P value
Maternal age	22.4±2.8	21.8±3.1	0.07
Gestational age	38.0±1.4	38.2±1.3	0.18
Indication for induction			
Hypertensive disorders	45 (27.8%)	52 (33.5%)	0.9
Postdatism	64 (39.5%)	58 (37.4%)	0.07
IUGR	11 (6.8%)	12 (7.7)	0.9
Oligohydramnios	22 (13.6%)	18 (11.6%)	0.1
IUFD	15 (9.2%)	12 (7.7%)	0.7
Others(Rh-negative, GDM)	5 (3.1%)	3 (1.9%)	0.7
Mean pre induction bishop score	2.0±0.8	2.1±0.7	0.2

Table 2: Change in bishop score.

	Group A (n= 162)	Group B (n=155)	P value
Mean change in score at 12 hours	5.2±1.81	4.9±1.76	0.1

Table 3: Labor profile.

Variable	Foley (n= 162)	PGE2 gel (n=155)	P value
Oxytocin augmentation	90 (55.5%)	74 (47.7%)	0.1
Abnormal FHR	28 (17.2%)	38 (24.5%)	0.1
Hyperstimulation	8 (4.9%)	25 (16.12%)	0.001
Tachysystole	15 (9.3%)	35 (22.5%)	0.001
Duration between induction and delivery(hours)	18.8±5.5	17.9 ± 5.3	0.1

Table 4: Delivery outcome

Variable	Group A (n= 162)	Group B (n=155)	P value
Spontaneous	125 (77.1%)	112 (72.2%)	0.3
Instrumental	6 (3.7%)	8 (5.2%)	0.12
LSCS	31 (19.1%)	35 (22.6%)	0.4
Indication of LSCS			
Abnormal FHR	6	12	
Failure to progress	17	11	
MSL	5	8	
Failed induction	3	4	

Table 5: Maternal and neonatal outcome.

Variable	Group A (n= 162)	Group B (n=155)	P value
Chorioamnionitis	8 (4.9%)	6 (3.8%)	0.8
APGAR(<7) in 1 minute	12 (7.4%)	16 (10.3%)	0.2
APGAR(<7) in 5 minute	3 (1.8%)	2 (1.3%)	0.16
NICU admission	9 (5.5%)	11 (7.0%)	0.1
NICU stay (days)	2 (1.2%)	2 (1.3%)	0.9

Table 4 shows delivery outcome of induction procedure. Statistically there was no difference in spontaneous vaginal delivery rate in both groups. In group A, 77.1% delivered spontaneously in comparison to 72.2% in group B. The rate of cesarean section was statistically insignificant (19.1% in group A and 22.6% in group B).

The most common indication for caesarian section was abnormal FHR in group B and failure to progress in group A.

4.9% and 3.8% respectively of group A and group B women developed chorioamnionitis as indicated by

occurrence of fever. The incidence of perinatal asphyxia shown by APGAR score at 5 minute was 1.8% in group A and 1.3% in group B. Admission to NICU was 5.5% in

Foley group and 7.0% in PGE2 gel group. However the morbidity in both the groups was not statistically significant.

Table 6: Satisfaction survey.

Survey	Group A (n= 162)	Group B (n=155)	P value
Felt a lot of discomfort			
At insertion	110 (67.9%)	48 (30.7%)	0.001
After 5 to 6 hours	42 (25.9%)	69 (44.5%)	0.006
Overall cervical ripening	48 (29.6%)	72 (46.4%)	0.001
Would choose this method again	106 (65.4%)	98 (63.5%)	0.4

Analysis of satisfaction questionnaire filled by the patients revealed that 65.4% in group A and 63.5 % in group B were satisfied by their method of induction and would choose their method again. The discomfort felt at the time of insertion was twice (67.9%) in group A compare to group B (30.7%) but as time progressed pain increased in group B. However in both the groups, women were able to cope with the discomfort (91.9% in group A and 88.4% in group B).

DISCUSSION

A number of studies have been done to find out the best ripening methods. However, there is no consensus on one method. An ideal cervical ripening agent is one which has its effect within short time without having any adverse effects on mother or fetus. It should also be cost effective to be used in developing country, easy to administer and widely available. The result of this study confirms that intracervical foley catheter used in cervical ripening is at par with dinoprostone gel. With respect to the demographic profile, both groups were comparable.

The mean change in bishop score in foley catheter was 5.2 as compared to 4.9 in PGE2 gel. This revealed that one did not have any advantage over the other when compared statistically.

St. Onge et al, also compared intracervical foley catheter with PGE2 gel and found both to be equally effective.

Number of women requiring oxytocin augmentation was higher in group A (55.5%) in comparison to 47.7% in group B. However the difference was not statistically significant. This is in agreement with study of Ezimokhul et al, and Rashid et al.^{8,9}

The incidence of tachysystole, hyperstimulation and abnormal FHR was higher in group treated with PGE2 gel which was statistically significant. Similarly, uterine hyperstimulation with PGE2 gel have been reported in study of Boulvain et al and Kelly et al.^{10,11} There was significantly more adverse reaction in study of Pennell et al also.¹²

In study by Henry et al, the rate of vaginal delivery within 24 hours was higher in PGE2 gel (29%) in comparison to foley catheter group (12%), but the rate was almost similar in vaginal delivery beyond 24 hours.¹²

The rate of LSCS in group A was 19.1% and in group B it was 22.6%. The LSCS rate found in our study is in agreement with study of Pennell et al, and Alfirevic et al.^{13,14} The most common indication was failure to progress in group A and abnormal fetal heart rate in group B.

The most important concern in using intracervical Foley catheter is infectious morbidity, but in our study the incidence of chorioamnionitis was only 4.9% in group A and 3.8% in group B. This is in contrast to study of Heinemann et al, which shows increased infection rate with mechanical induction of labor.¹⁵

Neonatal outcome in this study showed no significant difference between both groups with respect to APGAR score (at 1 and 5 minute) and NICU admission. In the study of Jozwiak et al, and Pennell at al, fetal outcome result were also comparable.^{13,16}

It has been suggested in a review of 11 reported studies that cervical ripening by ballooned catheter is similar to or better than other methods.¹⁷

In our study we had carried out a satisfaction questionnaire survey. It showed statistically significant difference in pain perception of women during both the methods. In the intracervical Foley catheter group, women reported more pain during insertion (67.9 % in group A and 30.7% in group B). However the discomfort decreased as time passes. In contrast the women with PGE2 gel had little discomfort during insertion but the pain increased along with cervical ripening. This is in agreement in study of Pennell and Henry et al.^{12,13} In spite of the discomfort felt during the entire cervical ripening phase, at the end of delivery women in both groups were satisfied with their induction method and told that they would prefer this method again(65.4% in group A and 63.5% in group B).

The total cost of foley catheter was much less than PGE2 gel.^{13,14}

CONCLUSION

It is best to differ the induction of labor until after ripening has commenced by natural means. However when maternal or fetal condition indicates then induction of labor by foley catheter shows no difference in effectiveness in comparison to other ripening methods. It is effective and has fewer side effects. Also there is no significant difference in mode of delivery or perinatal outcome. Advantage is, it causes less fetal distress and is a reversible method and avoids need for continuous monitoring in ripening phase. In contrast PGE2 gel is costly, has irreversible effect on uterine contraction and requires meticulous monitoring during labor. Therefore, to conclude foley catheter might be the method of choice in developing countries with limited facilities and where cost is a prohibitive factor.

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REFERENCES

1. Bishop EH. Pelvic scoring for elective induction. *Obstet Gynecol.* 1964;24:266-8.
2. Riskin-Mashiah S, Wilkins I. Cervical ripeing. *Obstet Gynecol Clin North Am.* 1999;26:243-57.
3. Stempel JE, Prins RP, Dean s. Preinduction cervical ripening: a randomized prospective comparison of the efficacy and safety of intravaginal and intracervical prostaglandin E2 gel. *Am J Obstet Gynecol.* 1997;176(6):1305-12.
4. Ulbjerg N, Ekman G, Malmstrom A. Ripeing of the human uterine cervix related to changes in glycosaminoglycans and collage nolytic activity. *J Obstet Gynecol.* 1983;147(6):662-6.
5. Trofatter KF, Bowers D, Standby RN, Gall A, Killam AP. Preinduction cervical ripening with prostaglandin E2 gel. *J Obstet Gynecol.* 1985;153(3):268-71.
6. Prins RP, Bolton RN, Mark C. Cervical ripening with intravaginal prostaglandin E2 gel. *J Obstet Gynecol.* 1984;63:697-702.
7. St. Onge RD, Connors GT. Preinduction cervical ripening: a comparison of intracervical prostaglandin E2 gel versus the foley catherer. *J Obstet Gynecol.* 1995;172(2):687-90.
8. Ezimokhai M, Nwabinelli JN. The Use of Foley Catherer in Ripening the unfavourable Cervix Prior to Induction of Labour. *Br J Obstet Gynaecol.* 1980;87(4):281-6.
9. Rashid M, Begum A, Chowdhury SB, Chowdhury S. Induction of labor by foley catheter method. A clinical study of forty cases. *Bangladesh J Obstet Gynaecol.* 1994;9(1):16-21.
10. Boulvain M, Kelly A, Lohse C, Stan C, Irion O. Mechanical methods for induction of labour. *Cochrane Data System Reviews.* 2001;ArtNo.:CD001233.
11. Kelly AJ, Kavanagh J, Thomas J. Vaginal prostaglandin (PGE2 and PGF2a) for indiction of labour at term. *Cochrane Database Syst Rev* 2003;Art. No.:CD003101.
12. Henry A, Madan A, Reid R, Tracy S. Outpatient foley catheter versus inpatient prostaglandin E2 gel for induction of labour: a randomised trial. *BMC Pregnancy and Childbirth.* 2013;13:25.
13. Pannel C, Henderson J, O'Neill M, McCleery S, Doherty D, Dickinson J. Induction of labour in nulliparous women with an unfavourable cervix: a randomised controlled trial comparing double and single balloon catherers and PGE2 gel. *BJOG.* 2009;116:1443-52.
14. Alfirevic Z, Kelly A, Dowsell T. Intravenous oxytocin alone for cervical ripening and induction of labour. *Cochrane Database Systematic Rev.* 2012;(3):Art. No.:CD001233.
15. Heinemann J, Gillen G, Sanchez-Ramos L, Kaunitz A. Do mechanical methods of cervical ripening increase infectious morbidity? A systematic review. *Am J Obstet Gynecol.* 2008;199(2):177-87.
16. Jozwiak M, Bloemenkamp K, Kelly A, Mol B, Irion O, Boulvain M. Mechanical methods for induction of labour. *Cochrane Database Systematic Rev.* 2012;(3):Art. No.:CD001233.
17. Sherman DJ, Frenkel E, Tovbin J, Arieli S, Caspi E, Bukovsky I. Ripening of the unfavorable cervix with extraamniotic catherer balloon: clinical experience and review. *Obstet Gynecol Surv.* 1996;51:621-7.

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