International Journal of Science and Research (IJSR)
ISSN (Online): 2319-7064
Index Copernicus Value (2015): 78.96 | Impact Factor (2015): 6.391

Comparative Study of Intracervical Foleys Catheter Instillation vs PGE2 Gel for Induction of Labour

Dr. Richa Jha[1], Dr. Renu Rohatgi[2]

[1]Senior Resident, Department of Obstetrics and Gynaecology, Nalanda Medical College and Hospital

[2]Professor and Head of the Department, Department of Obstetrics and Gynaecology, Nalanda Medical College and Hospital, Patna

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's 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, Nalanda Medical College and Hospital, Patna, during a period of one year from January 2016 to January 2017. 100 patients at term with a Bishop's score ≤3 with various indications for induction were randomly allocated to receive (50 pts) intra-cervical Foley's catheter or PGE2 gel (50pts). After 6 hours post induction, Bishop's score was noted, labou3,4 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 value < 0.001. However, there was no significant difference between the two groups. No difference in either the side effects or the caesarean section rates were observed. The induction to delivery interval was 16.01+5.50 hours in the foley's group (F) and and 16.8 + 3.8 hours in PGE2 group (P). APGAR scores and NICU admissions showed no difference between the two groups. Conclusion: The study shows both Intracervicalfoleyscathter and PGE2 gel are equally effective for cervical ripening.***

Keywords: Cervical ripening, PGE2 gel, Bishop's score, Foley's catheter, induction of labour

1. 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 preinduction 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, decreased caesarean section rate, increased 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 preinduction cervical ripening. The induction delivery interval, maternal and fetal outcomes and the need for augmentation of labor in these two groups were also compared.

2. Methods

The present study was carried out in the Department of Obstetrics and Gynaecology, Nalanda Medical College and Hospital, Patna, for a period of one year extending from January 2016 to January 2017. It was approved by ethical committee of the institution. All the cases fulfilling the inclusion 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

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.
- 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 <0.005 was considered statistically significant with confidence limit of 95%

3. Results

Group F and Group P had 50 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±SD, p <0.001) and in group P it was 5.15 +1.60 (p < 0.001). No significant difference in the mean changes in the two groups could be established.

1. Demographic Profile

Variables	Group F	Group P	P Value
Maternal Age	22.8 ± 3.28	22.3 ± 3	0.55
Gestational Age	38.48 ± 1.35	38.43 ± 1.35	0.78
Indication for Induction			
• Post datism	23 (46%)	26 (52%)	
• PIH	10 (20%)	12 (24%)	
Oligohydroamnios	11 (22%)	10 (20%)	
• IUFD	06 (12%)	02 (4%)	
Mean Pre induction Score	1.91 ± 0.7	1.90 ± 0.77	0.92

2. Change in Bishop's 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

3. Need for Augmentaton

Mode of Augmentation	Group F	Group P	P value
• None	04	03	1.000
• ARM	06	07	0.95
• Oxytocin	12	12	0.86
• ARM+ Oxytocin	15	16	0.92

4. Mode of Delivery and Induction- Delivery Interval

Variable	Group F	Group P	P Value
• Spontaneous	33	35	0.83
• Instrumental	04	03	1.00
• Lscs	13	12	1.00
• Total	50	50	
Induction-Delivery Interval	16.01 ±5.50	16.85±3.81	0.073

5. Neonatal Outcome

VARIABLE	Group F	Group P	P value
• MAS	02	03	1.00
• LSCS FOR FD	09	09	0.77
• 1' APGAR <7	06	07	0.756
• NICU Admission	14	12	0.796

The need for further augmentation of labour was studied in this study (Table 3). Delivery without any need for augmentation was seen in 4 patients in Foley's group and 3 patients in PGE2 group. In Foley's catheter group, need for augmentation of labor was required by doing ARM (n = 6), oxytocin infusion (n = 12) and both ARM + oxytocin in (n = 15) patients. In PGE2 gel group, 7 patients required ARM, 12 patients required oxytocin and 16 patients required both ARM + oxytocin. There was no statistically 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 66% (n = 33) spontaneous deliveries whereas group P had 70% (n = 35). Instrumental delivery using ventouse / forceps was required in 4 patients in F group and 3 patients in P group.The need for operative intervention (LSCS) was also not significant in both the groups. LSCS was done in 13 patients (26%) in F group and 12 patients (24%)in P group. Induction to delivery interval was 16.01±5.50 in F group and 16.85±3.81 in P group.

LSCS was done for fetal distress in group F for 9 cases and in group P for 9 cases. The other indications for LSCS being failure to progress (4 and 3 respectively and failure of induction

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). 28% of babies in group F (n = 14) and 24% of babies in group B (n = 12) got admitted in NICU. However the morbidity in both the groups was not statistically significant .

4. Discussion

The results of this study confirm that both Foley's catheter and PGE2 gel are equally effective in preinduction cervical ripening. The mean change in Bishops score in Foleys catheter 5.10±1.55 ($p<0.001$) and PGE2 gel 5.14 ± 1.60 ($p<0.001$)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 theoretical concerns regarding the introduction of infection with the use of Foleys catheter. In this study, there was no infectious morbidity. Similar was the observation of St. Onge and Conners, Jozwiak M and Anthony et al.
The need for oxytocin induced augmentation of labour 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.

The induction delivery interval showed no significant difference in the two groups. The mean I-D internal 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 fetal outcome results were also comparable in both groups.

A study by Rabindranath et al. concluded that extra-amniotic Foley catheter balloon is more effective than intracervical PGE2 gel for preinduction cervical ripening. Similar results were also found by another study, SciscioneAC et al. concluded that use of Foley catheter result in higher post-induction Bishop score, greater change in Bishop score and shorter induction time than PGE2. Ghezz et al. also concluded that Foley catheter could be a better alternative then intravaginal PGE2 gel for cervical ripening. Sherman [18] et al. showed the change in cervical ripening around score 4 when intracervicalfoley catheter was used as inducing agent.

The total cost of Foleys catheter was much less than PGE2 and hence could prove to be an effective method with less complications for cervical ripening in low resource settings like ours.

5. 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.

6. Conflict of interest

None declared

References

[1] World Health Organization. Department of reproductive health and research. WHO recommendations for induction of labour. Geneva, Switzerland: World Health Organisation; 2011:32.
[2] Tofatter KF, Bowers D, Standby RN, Gall A, Killam AP. Pre-induction cervical ripening with prostaglandin E2 gel. Am J Obstet Gynecol. 1985;153:268-71.
[3] National institute for clinical excellence. Clinical guidelines for induction of labour, Appendix-E. London: NICE; 2001.
[4] St. Onge RD, Conners GT. Preinduction cervical ripening: a comparison of intra-cervical PGE2 gel versus the Foley catheter. Am J Obstet Gynecol. 1995;172:687-90.
[5] Embrey, Mollison BG. The unfavourable cervix and induction of labour using a cervical balloon. BJOG. 1967;74:44.
[6] Obed JY, Adewole IF. The unfavourable cervix: improving the Bishop score with the Foley´s catheter. West Afr J Med. 1994;13(4):209-12.
[7] Sherman DJ, Frenkel E, Toblin J, Arieli S, Caspi E, Bukovasky I. Ripening of the unfavourable cervix with extra-amniotic catheter balloon: clinical experience and review. Obstetrical and Gynecological Survey. 1996;51(10):621-7.
[8] Arias F. Pharmacology of Oxytocin and Prostaglandins. Clinical Obstetrics and Gynecology. 2000;43(3):455-68.
[9] James C, Peedicayil A, Seshardi L. Use of the Foley catheter as a cervical ripening agent prior to induction of labour. International Journal of Gynecology and Obstetrics. 1994;47(3):229-32.
[10] Sandhu SK, Arora S. J ObstetGynae India. 1984;34:226.
[11] Sorensen SS, Brocks V, Lenstrup C. Induction of labour and cervical ripening by intracervical prostaglandin E2. Obstet Gynecol. 1985;65:110-4.
[12] Ghanaei MM, Sharami H, Asgari A. Labour induction in nulliparous women: a randomized controlled trial of Foley catheter with extra amniotic saline infusion. J Turkish-German GynecolAssocm. 2009;10:71-5.
[13] Niromanesh S, Mosavi-Jarrahi A, Samkhaniani F. Intracervical Foley catheter balloon vs. prostaglandin in preinduction cervical ripening. International Journal of Gynecology and Obstetrics. 2003;81:23-7.

[14] Jaya R, Rani S. Preinduction cervical ripening with endocervical PGE2 gel and a placebo control study. J ObstetGynecol India. 1994;537-42.
[15] Jozwiak M, Bloemenkamp K, Kelly A, Mol B, Irion O, Boulvain M. Mechanical methods for induction of labour. Cochrane Database Systematic Rev. 2012;(3):CD001233.
[16] Anthony C, Sciscione DO, Helen M. A prospective, randomized comparison of Foley catheter insertion vs. intracervical PGE2 gel for preinduction cervical ripening. Am J Obstet Gynecol. 1999;180:55-9.
[17] Dewan F, Ara AM, Begum A. Foley's catheter versus prostaglandin for induction of labor. Singap J ObstetGynaecol. 2001;32:56-63.
[18] Hertelendy F, Zakar T. Prostaglandins and the myometrium and cervix. Prostaglandins LeukotEssent Fatty Acids. 2004;70:207-22.
[19] Pennell 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 catheters and PGE2 gel. BJOG. 2009;116:1443-52