Comparison of the safety and efficacy of intracervical Foley's catheter versus PGE₂ gel for induction of labour at term

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ABSTRACT

Background: Before the induction of labour cervical ripening is needed for the success of induction to reduce the complication and diminish the rate of cesarean section and duration of labour. Various mechanical methods like Foley's catheter are effective but not much popular because of infection and pharmacological preparations which have more side effects, are used for cervical ripening. Therefore study has been conducted to compare the efficacy and safety of intra cervical Foley's catheter versus PGE₂ gel for induction of labour at term. The aims and objectives of this study was to success of induction of labour depends on the cervical status at the time of induction.

Methods: A prospective comparative study was conducted in the department of obstetrics and gynecology, L.G. hospital (AMCMET Medical college), Ahmedabad, during period of July 2019 to December 2019. 100 patients at term with a Bishop’s score with various indications for induction were randomly allocated to receive (50 patients) intra cervical Foley's catheter or PGE₂ gel (50 patients). Post induction Bishop’s score was noted after 6 hours, 12 hours, 24 hours. Statistical methods used were Student t test and Chi square test to statistically compare the two groups. Differences with a p value of <0.005 was considered statistically significant with confidence limit of 95%.

Results: The groups were comparable with respect to maternal age, gestational age, parity, indication of induction and initial bishops score. Both 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. Fetal outcome was noted in NICU admission and fetal death. No significant difference between two groups.

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

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

INTRODUCTION

Cervical ripening refers to a preparation of the cervix for induction of labour by promoting effacement and dilatation which is measured by Bishop’s score.¹

Poor Bishop’s score <6 have high failure rate so increased cesarean delivery, maternal fever, fetal hypoxia. To decrease the induction failure cervical ripening is done by various methods.

The success of induction depends upon the cervical status at the time of induction.²

Cervical ripening achieved by mechanical and pharmacological method.³⁴ Currently types of intracervical Foley's catheter available for induction. They causes mechanical dilation and stimulates endogenous release of prostaglandins by stripping the fetal membranes and release of lysosomes from decidual cells.
Use of Foley's catheter is associated with reduced induction delivery interval and decreases cesarean section rate. Chances of infections are very less if aseptic precautions are taken.5,6

Intra cervical application of PGE2 gel is also found effective for ripening of cervix because it can have a combined contraction inducing and ripening of cervix. PGE2 gel can cause connective tissue softening, effacement and uterine contraction.7,8

**Objective**

The purpose of the study was compare the efficacy of intracervical Foley's catheter with PGE2 gel for pre induction cervical ripening. Induction to active phase of labour interval, maternal and fetal outcome were compared.

**METHODS**

Patients at term with various indications for induction of labor with <6 Bishop’s score admitted in LR of LG for period of 6 months.

There were total 100 patients induced in study. Patients were randomly allocated to either Foley's catheter (group F=50) or PGE2 gel (group P=50) group.

Patients were examined thoroughly by taking history and obstetrics examination.

After fulfilling of inclusion and exclusion criteria and taking informed written consent.

**Inclusion criteria**

Singleton pregnancy with live fetus, >37 weeks of pregnancy, cephalic presentation, Bishop’s score <6, intact membranes, reactive fetal heart rate.

**Exclusion criteria**

Multiple pregnancy, malpresentation, absent membranes, antepartum hemorrhage, severe pre eclampsia and eclampsia, previous uterine scar, cephalopelvic disproportion, C/I to hypersensitivity to prostaglandins, medical diseases e.g. heart and renal diseases.

**Foley's catheter**

An 18 size Foley's catheter 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 balloon. The balloon was pulled up to the internal os. Catheter was tapped with thigh. Prophylactic antibiotics were given to each patient.

**Prostaglandin gel**

PGE2 gel in pre filled sterile preparation containing 0.5 mg of dinoprostone per 3 gm (2.5 ml) of gel. After exposing the cervix by speculum 0.5 mg of PGE2 was inserted intra cervically from a loaded syringe.

All patients were monitored for progress of labour according to partogram and fetal wellbeing. Post induction Bishop’s score will be assessed at 6 hours, 12 hours preferably by the same person.

**Primary outcome**

Post induction Bishop’s score was assessed every 4 hourly preferably by the same person.

**Secondary outcome**

Demographic profile, gestation age, improvement of Bishop’s score, induction to active labour time, induction-delivery interval, mode of delivery and feto-maternal outcome were noted.

Failure of induction was declared if patient failed to go in active phase of labor within 48 hours of induction.

**RESULTS**

Group F and group P had 50 randomized patients each. Both the group were comparable with respect to the maternal age, gestational age, indication for induction and pre induction bishops score.

In this present study improvement in the bishops 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).

**Demographic profile**

Table 1 shows, no significant statistical difference in indication for induction for both the groups. Group F had n=30 post datism where group P had n=27.

**Table 1: Demographic profile.**

| Variables             | Group F | Group P | P value |
|-----------------------|---------|---------|---------|
| Maternal age          | 25.8±3.28 | 25.3±3  | 0.55    |
| Gestational age       | 38.48±1.35 | 38.43±1.35  | 0.78    |
| Indication for induction |         |         |         |
| Post datism           | 30      | 27      |         |
| PIH                   | 07      | 05      |         |
| Oligohydroamios       | 07      | 12      |         |
| IUFD                  | 02      | 03      |         |
| Others                | 04      | 03      |         |
| Total                 | 50      | 50      |         |
| Mean preinduction score | 1.91±0.7 | 1.90±0.77 | 0.92    |
Group F had n=07 oligohydramnios where group P had n=12.

**Changes in bishops score**

In Table 2, pre induction Bishops score in group F was 1.91±0.70 and in group P it was 1.90±0.77; however no significant difference in the mean in these two groups.

| Bishop’s score                  | Group F     | Group P     | 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    |

**Mode of delivery and induction delivery interval**

Table 3 shows no significant statistical difference in spontaneous vaginal delivery in both the groups. Group F had n=30 spontaneous deliveries whereas group P had n=35. Group F had n=05 instrumental deliveries where group P had n=08. The need of operative intervention (LSCS) was also not significant in both the groups.

| Variables                        | Group F | Group P | P value |
|----------------------------------|---------|---------|---------|
| Spontaneous                      | 30      | 35      | 0.83    |
| Instrumental                     | 05      | 08      | 1.00    |
| LSCS                             | 15      | 17      | 1.00    |
| Total                            | 50      | 50      |         |
| Induction delivery interval      | 16.01±5.50 | 16.85±3.81 | 0.073  |

**Fetal outcome**

Table 4 shows, NICU admissions were slight more in group P (n=17) where in Group F (n=13). Baby back to mother in group F (n=37) where in group P (n=33).

|                      | Group F | Group P |
|----------------------|---------|---------|
| Baby back to mother  | 37      | 33      |
| NICU admissions      | 13      | 17      |
| Total                | 50      | 50      |
| Mean of fetal outcome| 16.01±5.50 | 16.85±3.80 |

**Indications for LSCS due to complications**

In Table 5, fetal distress was an indication for LSCS in group F (n=10) was less than in group P (n=21). Because of mechanical method (Foley’s catheter) there no any drug effect to fetus other than pharmacological method (PGE₂ gel).

|                      | Group F | Group P |
|----------------------|---------|---------|
| Fetal distress       | 10      | 21      |
| Meconium stained liquor | 05    | 11      |
| Others               | 06      | 08      |

**Maternal complications**

Table 6 shows hyperstimulation in mother was more in group P (n=02) as compared to group F (n=00).

|                      | Group F | Group P |
|----------------------|---------|---------|
| Hyperstimulation     | 00      | 02      |
| Tachysystole         | 00      | 02      |
| Fever                | 02      | 04      |

**DISCUSSION**

The results of this study confirm that both Foleys catheter and PGE₂ gel were equally effective in preinduction cervical ripening. The mean change in bishops score in Foleys catheter 5.1±1.55 (p<0.001) and PGE₂ gel 5.14±1.60 (p<0.001) are highly significant.

However a comparison between the groups revealed that one method did not confer a statistically significant advantage over the other.

The induction delivery interval showed no significant difference in the two groups. The mean I-D interval was 16.01±5.5 hours in Foleys catheter and 16.85±3.81 hours in PGE₂ gel group.

Maternal complications showed that there were more hyperstimulation in PGE₂ gel as compare to Foleys.

This study showed there were more repeat insertion of PGE₂ gel intracervically, which may increase the risk of tachysystole and possibility of chorioamnionitis.

As we can see that in my study NICU admissions were more in group P as compared to group F.

Limitations of this study are unsuitable for outpatient management and unable to give informed consent or consent was declined.

**CONCLUSION**

In conclusion this study has shown that for pre induction cervical ripening there is no significant difference in efficacy and safety between intra cervical PGE₂ gel and intra cervical Foleys catheter.
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Ethical approval: The study was approved by the Institutional Ethics Committee

REFERENCES

1. National Institute for Clinical Excellence. Clinical guidelines for induction of labour, Appendix-E. London: NICE; 2001.
2. St. Onge RD, Conners GT. Preinduction cervical ripening: a comparison of intracervical PGE2 gel versus the Foley catheter. Am J Obstet Gynecol. 1995;172:687-90.
3. Dewan F, Ara AM, Begum A. Foley’s catheter versus prostaeglandin for induction of labour. Singapore J Obstet Gynaecol. 2001;32:56-63.
4. Sciscione AC, McCullough H, Manley JS, Shlossman PA, Pollock M, Colmorgen GH. A prospective, randomized comparison of Foley catheter insertion versus intracervical prostaglandin E2 gel for preinduction cervical ripening. Am J Obstet Gynecol. 1999;180(1):55-9.
5. Embrey MP, Mollison BG. The unfavourable cervix and induction of labour using a cervical balloon. J Obstet Gynaecol Br. Common W. 1967;74:44.
6. Boulvain M, Stan CM, Irion O. Membrane sweeping for induction of labour. Cochrane Database Systemat Rev. 2005(1).
7. Thomas IL, Chenoweth JN, Tronc GN, Johnson IR. Preparation for induction of labour of the unfavourable cervix with Foley catheter compared with prostaglandin. Aust NZ Obstet Gynaecol. 1986;26:30-5.
8. 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.
9. 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.
10. James C, Peedicayil A, Seshardi L. Use of the Foley catheter as a cervical ripening agent prior to induction of labour. Int J Gyn Obst. 1994;47(3):229-32.
11. Chowdhary A, Bagga R, Kalra J, Jain V, Saha SC, Kumar P. Comparison of intracervical Foley catheter used alone or combined with a single dose of dinoprostone gel for cervical ripening: a randomised study. J Obstet Gynaecol. 2019;39(4):461-7.

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