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Original Research Article

Comparison of the safety and efficacy of intracervical Foleys catheter versus PGE_2 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 Foleys 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 Foleys catheter versus PGE_2 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 Foleys catheter or PGE_2 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 Bishops score, 5.10±1.55 and 5.14±1.60 for Foleys catheter and PGE_2 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 Foleys catheter and PGE_2 gel were equally effective in pre induction cervical ripening.

Keywords: Cervical ripening, Foleys catheter, Induction of labor at term, PGE_2 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.[3,4] Currently types of intracervical Foleys 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 Foleys 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 PGE_2 gel is also found effective for ripening of cervix because it can have a combined contraction inducing and ripening of cervix. PGE_2 gel can cause connective tissue softening, effacement and uterine contraction.[7,8]

Objective

The purpose of the study was compare the efficacy of intracervical Foleys catheter with PGE_2 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 Foleys catheter (group F=50) or PGE_2 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.

Foleys catheter

An 18 size Foleys 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

PGE_2 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 PGE_2 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 oligohydroamios 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.

Table 2: Changes in Bishop's score.

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.

Table 3: Mode of delivery and induction delivery interval.

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).

Table 4: Fetal outcome.

	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 (PGE_2 gel).

Table 5: Indications for LSCS due to complications.

	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).

Table 6: Maternal complications.

	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 PGE_2 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 PGE_2 gel 5.14±1.60 ($p<0.001$) are highly significant.[2,4]

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 PGE_2 gel group.[3]

Maternal complications showed that there were more hyperstimulation in PGE_2 gel as compare to Foleys.

This study showed there were more repeat insertion of PGE_2 gel intracervically, which may increase the risk of tachysystole and possibility of chorioamnionitis.[11]

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 PGE_2 gel and intra cervical Foleys catheter.

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

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