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A Comparative Study of Intra-Cervical Foley's Catheter and PGE2 Gel for Pre-Induction Cervical Ripening

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ABSTRACT

Background: *To increase the success of labour induction, to reduce the complications and to diminish the rate of cesarean section and duration of labour, Cervical ripening is needed before the induction of labour. Even though pharmacological preparations are in widespread use for cervical ripening, it causes side-effects and complications. Foley's catheter balloon (effective mechanical method) have not gained much attention because of infection. The efficacy and safety of extra amniotic Foley catheter balloon has been proved in this study by comparing it with intra-cervical prostaglandin E2 (PGE2) gel.*

Objective: *The success of induction of labour depends on the cervical status at the time of induction was analyzed in this study. For effective cervical ripening, Foley's catheter and PGE2 gel are used in this work. Further, the efficacy of intra cervical Foley's catheter and intra cervical PGE2 gel in cervical ripening for the successful induction of labour are compared and briefly elongated.*

Methods: *In the department of obstetrics and gynaecology a randomized, comparative study was conducted. 200 patients at term with a Bishop's score of ≤3 with various indications for induction were randomly allocated to receive (100 pts) intra-cervical Foley's catheter or PGE2 gel (100 pts) was taken in account during a period of one year from July 2015 to June 2016.*

Bishop's score was noted, labor was augmented if required after 6 hours of post induction. Chi square test and t test was used for Statistical analysis in this work

Results: *The groups were comparable with respect to maternal age, gestation age, indication of induction and initial Bishop's score. A significant change in the Bishop's score was showed by both the groups, 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.*

In both the groups, no significant difference in the side effects and caesarean section was found. 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).There is no significant difference between the two groups in the aspects of Apgar scores, birth weights and NICU admissions.

Conclusion: *This study shows that both Foley's catheter and PGE2 gel are equally effective in pre induction cervical ripening with better neonatal outcome with Foley's catheter compared to that of PGE2 gel.*

Keywords: *Cervical ripening, PGE2, Foley's catheter, Induction of labour.*

INTRODUCTION

The process of preparing the cervix for induction of labor by promoting effacement and dilatation as measured by Bishop's score refers to Cervical ripening.[1] Safe, simple and effective methods should be carefully considered in the Induction of labour. Consistency, compliance and configure-tion of cervix[2] are the major concerns for the success of induction.

There may be increased rate of caesarean section delivery, maternal fever and fetal hypoxia[3], in case of low Bishops score. Therefore a simple and effective method for pre induction cervical ripening is of use.

Mechanical techniques such as introduction of trans-cervical Foleys catheter,[4] can be used for achieving Ripening of cervix. 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.[5]

Reduced induction delivery interval, decrease caesarean section rate, increase rate of spontaneous vaginal delivery[6] are associated with the use of catheter. Chances of infection are no more than that of the usual hospital rate if strict aseptic precautions are observed.[7] For ripening of cervix, Intra-cervical application of PGE2 gel is found to be effective as it can have a combined contraction inducing and cervical ripening effect.[8]It has been used 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.[9] PGE2 gel can be used in cases of heart disease, PIH and eclampsia also. [10] The purpose of this study is 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 labour in these two groups are also compared.

METHODS

From July 2015 to June 2016, the present study was carried out in the department of obstetrics and gynaecology for a period of one year. 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. For this a total case of 200 numbers was taken in account.

INCLUSION CRITERIA

Primigravida
≥37 weeks of gestation
Singleton pregnancy
Cephalic presentation
Bishop's score ≤ 3
Intact membranes

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. Individual patients are questioned in detail and examined thoroughly for the study. The patients last menstrual period was ascertained and correlated clinically.

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. Other methods such as artificial rupture of membrane (ARM) and/or oxytocin administration are implemented for assessing the Need of augmentation of labour. If the patient failed to go in active phase of labour

within 48 hours of induction then the failure of induction was declared.

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 50 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

The two groups were statistically compared by using the student's t test and Chi square test. Differences with a p value of < 0.05 was considered statistically significant with the confidence limit of 95%.

RESULTS

TABLE -1: Demographic Profile

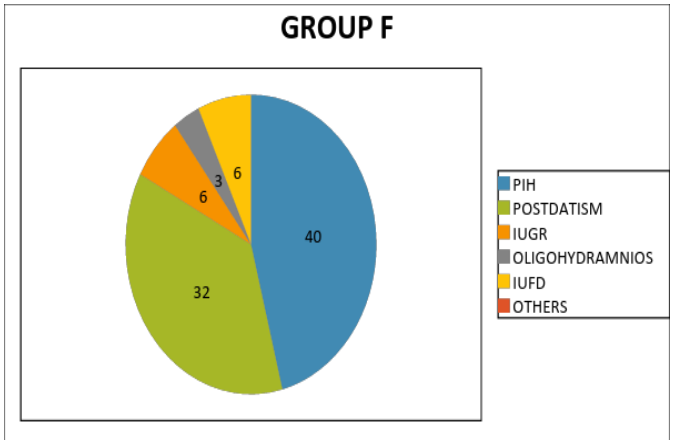
Group P	Group F	Variables
22-25	22 -25	Maternal Age
38-40	38-40	Gestational Age

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.

TABLE -2: Indication For Induction of Labour

Group P	Group F	Indication
37 (37%)	40 (40%)	Pih
30	32(32%)	Postdatism
7	6	Iugr
4	3	Oligohydramnios
7	6	Iufd
15	13	Others

DIAGRAM 1: Indication for Induction in Group F and Group P



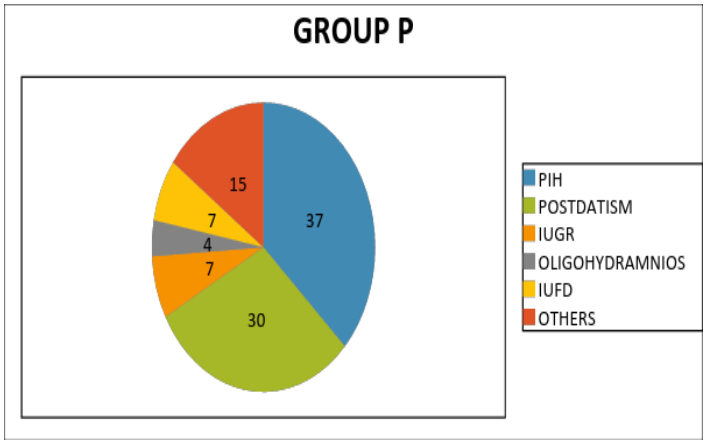


Table -3: Need For Augmentation

P Value	Group P	Group F	Mode Of Delivery
0.62	27	23	None
0.62	11	8	Arm
0.88	38	39	Oxytocin
0.42	24	30	Arm +Oxytocin

In this regards, the need for augmentation of labour was studied. Labour ensued in 23 patients of Group F compared with 27 patients of Group P. G group F need for augmentation of labour by doing ARM for eight patients (8), oxytocin thirty-nine patients (39) and both ARM+OXYTOCIN

for thirty patients (30) patients. Group P need for augmentation of labour by doing ARM for eleven patients (11), oxytocin for thirty-eight patients (38) and both ARM+OXYTOCIN for twenty-four patients (24) patients. No significant difference was obtained for augmentation in both groups.

TABLE -4: Mode of Delivery

Group P	Group F	Mode Of Delivery
76	84	Spontaneous
6	6	Instrumental
18	10	Lscs

Number of LSCS in Group P is 18 whereas it is 10 in Group F. The most common indication for LSCS in group P is fetal distress whereas in group F it is non progress of labour. Though the labour is prolonged, neonatal outcome is better with group F.

GRAPH 1: Mode of Delivery

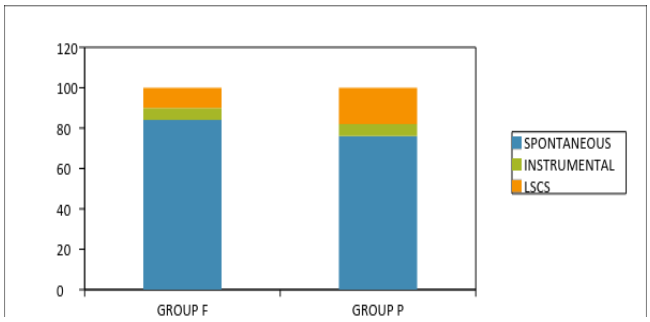
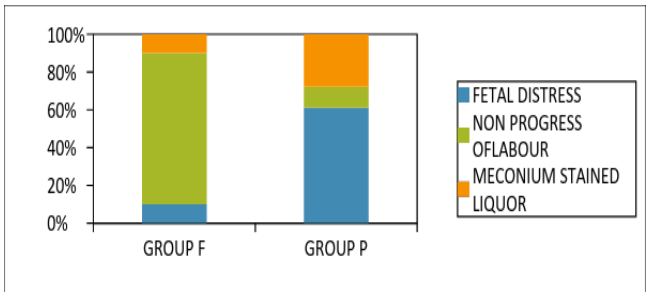


TABLE -5: Mean Phases of Labour

P-Value	Group P	Group F	
>0.1	10±6.8	8.5±5.1	Latent Phase
< 0.05	13.6±16.9	11.08±5.6	Time Of Delivery

There is significant difference in the induction – delivery interval and labour is slightly prolonged in group F compared to group P.

GRAPH: 2 LSCS Indication



Fetal distress is more with group P whereas non progress of labour is more with group F.

TABLE – 6: Maternal Effect

Group P	Group F	
2	0	Tachysystole
2	6	Atony
4	0	Uterine Hypertonicity

TABLE -7: Neonatal Outcome

Group P	Group F	Variables
4	2	Meconium Aspiration Syndrome
11	1	Lscs For Fetal Distress
4	1	1 Minute Apgar <7
12	5	Nicu Admission
1	0	Neonatal Death

DISCUSSION

Both the Foley's catheter and PGE2 gel are equally effective in preinduction of cervical ripening was confirmed based on the results studied. One method did not confer a statistically significant advantage over the other was revealed based on the comparison between the two groups. There have been theoretical concerns regarding the introduction of infection with the use of Foley's catheter. No infectious morbidity was identified in this study as the same observation was seen of St. Onge and Conners, Jozwiak M and Anthony C et al. [11] 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. [12] The rate of LSCS in Group F was 21% and 19% in Group P (p = 0.88) respectively. 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. [13]There was no association of increased rate of cesarean section with the Foley's catheter PGE2 gel usage. 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

CONCLUSION

Nil difference in efficacy between intra cervical PGE2 gel and intra cervical Foley's catheter pre-induction cervical ripening is identified in this study. Also, other factors like induction delivery, interval maternal, neonatal outcome and need for oxytocin for further augmentation were similar in both the groups. Both methods are complementary to each other was finally concluded.

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