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Comparative Study between Intra Cervical Foleys Catheter and Pge2 Gel for Pre Induction Cervical Ripening

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ABSTRACT
Introduction: *Normal labour is the process of expulsion of a viable fetus to the outside world. Cervical ripening refers to a process of preparing the cervix for induction of labor by promoting effacement. This study aimed to compare the efficacy of intra-cervical Foley's catheter with PGE2gel forpre-induction cervical ripening.*
Material and Methods: *The study was carried out in admitted patients in the Department Of Obstetrics and gynaecology at Shrimati Heera Kunwar Baa Mahila Hospital in association with Jhalawar Medical College, Jhalawar, Rajasthan. This was an prospective study conducted on 140 patients during January2020 to December 2020.*
Result: *The two groups of women were similar with respect to age, parity, gestational age. There was a significant increase in post-induction Bishop's score inboth the study groups. The rate of vaginal delivery was 85.7% and 78.5% in group 1 and group 2 respectivelywhich had no significant difference p >0.05. In PGE2 gel group one patient had tachysystole, one patient had vomiting, one had diarrhea and one developed fever and One cases of cervical tear noted whereas in Foley's group one patient developed fever and a manual removal of placenta. Overall incidence of side effects was higher in PGE2 gel group (7.14% vs 2.85% with p value >0.05).*
Conclusion: We c*onfirmed that both PGE2 gel and intra-cervical Foley's catheter are effective methods for pre-induction cervical ripening. However, with Foley's catheter there was significant improvement in Bishop's score and shorter induction delivery interval as compared to PGE2 gel.*
Keywords: *Cervical Ripening, PGE2 gel, Foleys catheter.*

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I. INTRODUCTION

Normal labour is the process of expulsion of a viable fetus to the outside world. This process begins with the commencement of true labor contraction and ends with the expulsion of the placenta. During pregnancy, the cervix remains firm and closed to ensure the integrity of the pregnancy. Toward the end of the pregnancy, the cervix becomes softer and more distensible in a process known as cervical ripening. Cervical ripening greatly facilitates labor and augments the chances of vaginal delivery. The state of the cervix is clearly related to the success of labor induction, duration of labor, and likelihood of vaginal delivery.[1]

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.[2]Induction of labour should be safe, simple and effective. The success of induction depends upon the consistency, compliance and configuration of cervix.3With low Bishops score, there may be increased rate of caesarean section delivery 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 asintroduction of intra-cervical Foleys catheter.[5,6] It can cause mechanical dilatation of cervix and stimulates endogenousrelease 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, decrease caesarean section rate, increase 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 forripening 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 PGE2causes direct softening of cervix by a number of different mechanisms. It isbelieved that dinoprostone exerts its uterine effects via direct myometrial stimulation, but the exact mechanism of action is unkown. Other suggestedmechanisms include the regulation of cellular membrane calcium transport

and ofintracellular concentrations of cyclic 3',5'-adenosine monophosphate. It can causeconnective tissue softening, cervical effacement and uterine activity.[12,13]

This study aimed to compare the efficacy of intra-cervical Foley's catheter with PGE2gel forpre-induction cervical ripening.

II. MATERIAL AND METHODS

The study was carried out in admitted patients in the Department Of Obstetrics and gynaecology at Shrimati Heera Kunwar Baa Mahila Hospital in association with Jhalawar Medical College, Jhalawar, Rajasthan. This was an prospective study conducted during January2020 to December 2020. All the cases was included in our study during study period which fulfill our inclusion and exclusion criteria with written and informed consent.
Inclusion Criteria: 1. Primigravida 2. >/=39weeks of gestation 3. Singleton pregnancy 4. Cephalic presentation 5. Bishops score B<3.
Exclusion Criteria: 1. Multiple pregnancy 2. Mal-presentation 3. Absent membranes 4. APH -placenta previa major degree.

The patients was randomly allocated to either Foley's catheter or PGE2 gelmethod. The Bishop's score was determined earlier. Each patient was questioned in detail and examined thoroughly. Last menstrual period (LMP) was ascertained and correlated clinically. Post induction Bishop's score was assessed after 6 h of induction preferably by the same person. Demographic profile, gestation age, improvement of Bishop's score, induction-delivery interval, mode of delivery and feto-maternal outcome wasnoted. Dose repetition of PGE2 gel was consider if postinduction Bishop's score was B6 in both the groups. Need of augmentation of labor was assessed and implemented by other methods such as acute rupture of membrane (ARM) and/or oxytocin administration. Failure of induction was declared if patient failed to go in active phase of labor within 24 h of induction.

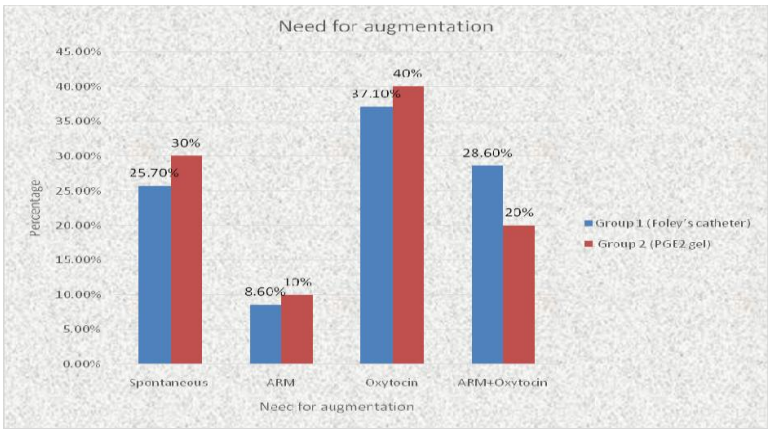
III. OBSERVATION AND RESULT

During the study period a total of 140 patients were included in the study. 70patients were induced with Prostaglandin gel and 70 patients with Foley balloon catheter. The majority (61.4%) patients in group 1 and 58.6% patients in group 2 were in age group 21-25 years. The majority 68.6% patients in group 1 and 65.7% patients in group 2 were of gestational age 39.1-40 weeks. The two groups of women were similar with respect to age, parity, gestational age.

Table 1: Change in Bishop score

Bishop Score	Group 1 (Foley's catheter)		Group 2 (PGE2 Gel)	
	Mean	SD	Mean	SD
Pre-Induction	1.74	0.27	1.62	0.82
Post-Induction	8.04	1.01	7.42	1.98
T-Value	50.42		22.64	
P-Value	<0.0001		<0.0001	

In table 1, there was a significant increase in post-induction Bishop's score inboth the study groups. However, it was observed that post-induction Bishop's score and mean change in Bishop's scores were significantly higher in Foley's catheter group as compared to PGE2 gel group.



As shown in graph 2, In group 1, 8.6% patients required ARM, 37.1% patients required oxytocin and 28.6% patients required both ARM + oxytocin whereas in group 2, need for augmentation of labor was required by doing ARM in 10%, oxytocin infusion in 40% and both ARM + oxytocin in 20%. Spontaneous labor ensued in 25.7% patients in group 1 as compared to 30% patients in group 2.

Graph 2: **Need for augmentation**

In the present study we found the rate of vaginal delivery was 85.7% and 78.5% in group 1 and group 2 respectivelywhich had no significant difference p >0.05.

Table 3: Comparison of induction-delivery interval

	Group 1 (Foley's catheter)		Group 2 (PGE2 Gel)		p-value
	Mean	SD	Mean	SD	
Induction Delivery Interval	12.2	4.8	15.47	5.3	<0.05

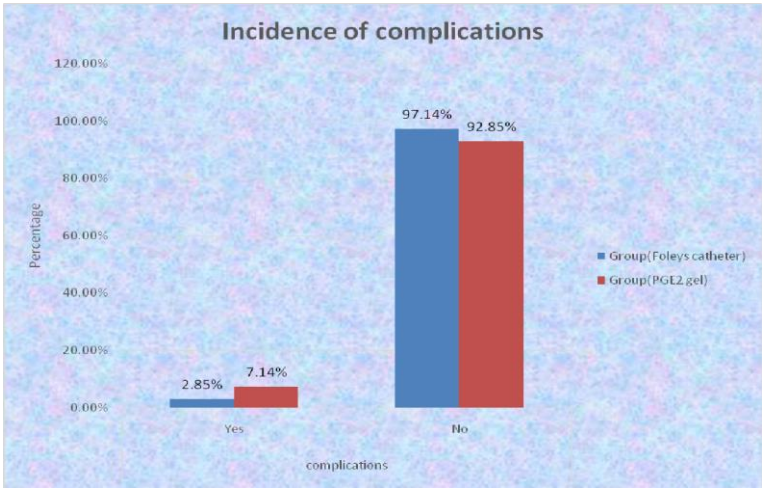
In table 3, we had shown that the induction to delivery interval was significantly lower for group 1 as compared togroup 2 p value <0.05.

Table 4: **Incidence of pain**

Pain	Group 1 (Foley's catheter)		Group 2 (PGE2 Gel)	
	Number	Percentage	Number	Percentage
No Pain	0	0	0	0
Mild Pain (1,2,3)	49	70	35	50
Moderate Pain (4,5,6,7)	14	20	21	30
Severe Pain (8,9)	7	10	14	20
P-Value	0.04			

Pain was analysed with visual analogue scale and found to be less in Foley balloon method than in intracervical prostaglandin gel. Initial insertion of Foley balloon is painless and they have pain only after removal of Foley catheter in most of the cases due to labour augmentation with Cytotec or oxytocin. 90 % of patients delivered with mild to moderate pain during the course of labour. The initial dilatation ofcervix up to 3 cm is painless. But in gel group the initial application itself caused pain and 50%of cases delivered with moderate to severe pain. The pain duration in gel group is more than Foley catheter group (Table 4).

In the present study in PGE2 gel group one patient had tachysystole, one patient had vomiting, one had diarrhea and one developed fever and One cases of cervical tear noted whereas in Foley's group one patient developed fever and a manual removal of placenta. Overall incidence of side effects was higher in PGE2 gel group (7.14% vs 2.85% with p value >0.05) (statistically not significant).



Graph 5: Incidence of complications

IV. DISCUSSION

This study compared intra-cervical Foley's catheter with PGE2 gel for pre-induction cervical ripening. In present study, the patients were equally distributed according to age and gestational age in weeks in Foley's catheter group and PGE2 gel group respectively which is comparable with the study done by Dharmavijaya MN et[14] al who also found similar results. In present study, the most common indication for induction of labor was pregnancy induced hypertension followed by postdated pregnancy. This is similar to the study conducted by Laddad MM et al.[15] The mean pre- induction and post- induction Bishop's score were 1.74±0.27 and 8.04±1.01 in Foley's catheter group whereas in PGE2 group, they were 1.62±0.82 and 7.42±1.98 respectively. P-value of pre-induction Bishop's score was 0.2469 which was statistically insignificant whereas the p-value of post induction bishop's score was 0.0211*, which was statistically significant. The mean change in Bishop's score in Foley's group was 6.30±0.74and that in PGE2 gel group was 5.84±1.16 and this difference was considered statistically significant ($p<0.0001$). Results are comparable to study conducted by Sciscione AC et al where the mean of post-induction Bishop's score in Foley's group was 6.5±1.63 and in PGE2 gel groupwas 5.1±2.3 with p value <0.0001(statistically significant) and mean change in Bishop's score (3.5 vs 2.7, $p=0.015$) is significantly higher in Foley's group. Another study conducted by St Ongo RD et al showed mean change in Bishop's score in Foley's group was 4.8±0.5 and inPGE2 gel group was 4.1±0.5 with p value <0.001, which was statistically significant.

Induction delivery interval was significantly shorter ($p<0.05$) in women who underwent cervical ripening with Foley's catheter. In some studies, it was found to be longer in Foley's catheter group than PGE2. However another study reported more efficacy of Foley's catheter expressed as a lower induction to delivery interval.

Present study findings demonstrate no significant difference in oxytocin augmentation in both groups, however some studies have shown an increased need for oxytocin induction and/or augmentation of labor after Foley's ripening, compared with PGE2 Both methods are similar in terms of the mode of delivery, but the risk of excessive uterine activity is higher with PGE2 group compared with Foley's group.

In PGE2 gel group one patient had tachysystole, one patient had vomiting, one had diarrhea and one developed fever whereas in Foley's group one patient developed fever. Overall incidence of side effects was higher in PGE2 gel group (5.7% vs 1.4% with p value >0.05) (statistically not significant).

V. CONCLUSION

The results of this study confirm that both PGE2 gel and intra-cervical Foley's catheter are effective methods for pre-induction cervical ripening. However, with Foley's catheter there was significant improvement in Bishop's score and shorter induction delivery interval as compared to PGE2 gel. It also has the advantage of simplicity, reversibility and lack of systemic as well as serious side effects.

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