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Research Article

Comparison of the efficacy of intra-cervical foley's catheter balloon with PGE_2 gel in pre-induction cervical ripening

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ABSTRACT

Background: The aim of this study was to compare the efficacy of intracervical Foleys catheter and intracervical PGE2 gel in preinduction cervical ripening.
Methods: This randomized, prospective study was conducted in the Department of Obstetrics and Gynecology, Government Medical College Srinagar from Mar 2011- Mar 2013. Total 200 patients at term with a Bishop's score <3 with various indications for induction were taken and randomly allocated to receive intracervical Foleys catheter (100pts) or PGE_2 gel (100pts). After 6 hours post induction, bishop's score was assessed. Various parameters noted were change in Bishop Score, induction delivery interval, mode of delivery fetal outcome and maternal complications. Statistical analysis was done using chi square test and t-test.
Results: The groups were comparable with respect to maternal age, gestational age, indication of induction and preinduction bishop's score. Both the groups showed significant change in the bishop's score, 5.3+1.1 &5.1+1.1for Foleys catheter and PGE_2 gel, respectively ($p<0.001$); however the difference between the two groups was not significant.14 cesarean sections (14%) were performed in group A and 20(20%) were performed in group B (NS). The induction to delivery interval was 15.34+5.3 h in group A and 14.2+5.2 h in group B ($p= 0.29$). Apgar score, birth weight, NICU admissions and maternal side effects showed no difference between the two groups.
Conclusions: This study shows that both Foleys catheter and PGE_2 gel are equally effective in pre induction cervical ripening.

Keywords: Cervical ripening, PGE_2 gel, Foleys catheter

INTRODUCTION

Induction of labor is a method by which pregnancy is terminated artificially any time after fetal viability is attained, for various indications by a method that aims to secure delivery.[1] According to American College of Obstetricians and Gynecologists - Induction of labor is undertaken when, in the opinion of the physician, the risks of delivery to the mother or fetes or both are less than the risk of continuing the pregnancy. Incidence of induction of labor is generally showing a rising trend.[3] The induction rates have increased from 9.5% in 1991 to 22.5% in 2006.[4]

The changes in the uterine cervix and lower uterine segment preceding the onset of labor are referred to as cervical ripening and seem essential to normal labor and delivery.[5] Cervical ripening is an integral part of the conditioning phase of parturition, and it occurs independently of uterine contractions.[6-8]

It is generally predicted that the patient with a poor bishop's score ≤3 have higher failure rates of induction.[8]It was also shown that a low bishop's score is

associated with increased rates of LSCS, maternal fever and fetal asphyxia.[9,10] To decrease this induction failure, cervical ripening by any method is the answer.

The purpose of this study was to compare the efficacy of intracervical Foleys catheter with PGE_2 gel for pre induction cervical ripening.

METHODS

This study was conducted in the Department of Obstetrics and Gynecology GMC Srinagar from Mar 2011-Mar 2013. Total of 200 cases were taken for the study which were divided by simple randomization into two groups with 100 patients in each group. Group A (100pts) underwent induction by intracervical Foleys catheter and group B (100pts) by intracervical PGE_2 gel. Patients at term with various indications for induction of labor were included in the study after a written consent.

Inclusion criteria

(a) Primigravida.
(b) ≥37 weeks of gestation
(c) Singleton pregnancy
(d) Cephalic presentation
(e) Bishop's score ≤3
(f) Intact membranes

Exclusion criteria

(a) Multifetal pregnancy
(b) Mal- presentation
(c) Absent membranes
(d) APH
(e) Medical disease e.g. heart disease, renal disease.

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 score was assessed after 6h of induction.

Demographic profile gestation age, improvement of bishop's score, induction delivery interval, and mode of delivery and fetomaternal outcome was noted.

Need of augmentation of labor was assessed and implemented by other methods such as rupture of membranes and /or oxytocin administration

Failure of induction was declared if patient failed to go in active phase of labor within 24 hrs of induction.

Student's t test and chi square test were used to statistically compare the two groups. Differences with a p value of <0.05 were considered statistically significant with the confidence limit of 95%.

RESULTS

Group A and Group B had 100 randomized patients each. Both the groups were comparable with respect to the maternal age, gestation age, indication for induction and pre induction bishop's score (Table 1).

Table 1: Demographic profile.

Variables	Group A n=100	Group B n=100
Maternal age	24.9+2.8yrs	24.6+3.3yrs
Indication for induction		
Elective	35	
Postdated Pregnancy	41	36
Oligohydramnios	7	37
IUGR	6	8
Gestational diabetes	5	7
Mellitus	6	5
Others		7

In this study improvement in the bishop's score in Group A was 5.3±1.1

(p<0.001) and in Group B it was 5.1±1.1(p<0.001); however no significant difference in the mean changes in the two groups could be established (Table 2).

Table 2: Change in bishop score.

Bishop score	Group A	Group B
Mean pre-induction bishop score	2.4±0.7	2.5±0.8
Mean post-induction bishop score	7.7±0.8	7.6±0.8
Mean change in score	5.3±1.1	5.1±1.1
	P=0.000	P=0.000

The need for further augmentation of labor was studied in this study. In Foleys catheter group, need for augmentation was required in 67 patients and in PGE_2 group it was required in 61 patients .There was no significant difference in need for augmentation in both the groups (Table 3).

Table 3: Need for augmentation and induction delivery interval.

Need for augmentation	Group A	Group B	P value
Spontaneous	33	39	
ARM	6	30	0.378
Oxytocin	28	24	
ARM + Oxytocin	33	7	
Induction-delivery interval	15.34± 5.3h	14.2± 5.2h	0.29

Table 4 shows no significant statistical difference in spontaneous vaginal delivery in both the groups. Group A had 82% spontaneous deliveries whereas group B had 78% spontaneous deliveries.

Table 4: Mode of delivery.

Variable	Group A n=100	Group B n=100	P value
Spontaneous	82	75	0.42
Instrumental	4	5	
LSCS	14	20	
Total	100	100	

The need for operative intervention was also not significant in both the groups. LSCS was done for foetal distress in group A for 7 cases and in group B for11 cases. The other indications for LSCS being failure of progress (six each) and failure of induction.

Table 5 shows that one minute and five minute Apgar score were similar in both the groups. The neonatal birth weights were also comparable in both the groups (2.77±0.51 in group A and 2.73±0.24 in group B). 8% of babies in group A and 12% of babies in group B got admitted in NICU. Overall fetal outcome was good in both the groups.

Table 5: Neonatal outcome.

Variable	Group A	Group B	P value
1 min Apgar score	7.8+0.5	7.8+0.6	0.632
5 min Apgar score	9.7+0.6	9.8+0.5	0.263
Mean birth weight (kg)	2.7+0.51kg	2.7+0.24kg	0.529
Admission to NICU	8	12	0.47
Fetal distress	9	13	0.49

DISCUSSION

The results of this study confirm that both Foleys catheter and PGE_2 gel are equally effective in pre induction cervical ripening. The mean change in bishop's score in Foleys catheter 5.3±1.1($p<0.001$) and PGE_2 gel 5.1±1.1 ($p<0.001$) were highly significant however, a comparison between the groups revealed that one method had no statistically significant advantage over the other .Similar were the observation of St onge and Conners[9] and Anthony et al.[11]

The need for augmentation of labor was 67% in group A and 61 % in group B. This is in agreement with studies done by Deshmukh et al and Tahira et al.[12,13]

The induction delivery interval showed no significant difference in the two groups .The mean I-D interval was 15.34±5.3h in Foleys group and 14.2±5.2h in PGE_2 group. Similar observations were made by Dewan et al and Deshmukh et al.[12-14]

The rate of LSCS in group A was 14% and19% in group B (p=0.52, NS).The most common indication in both the groups being fetal distress. Group A had cases of foetal distress and group B had 10 cases of foetal distress. The rate of LSCS in our study is agreeable.[9,11]

Fetal outcome data showed no significant difference between group A and group B with respect to birth weight (p=0.529), 1&5 minute Apgar score (p=0.263) NICU admission rate (8&12 respectively). Thus the present study showed that the foetal outcome results were also comparable in both the groups.

CONCLUSIONS

In conclusion this study shows that for pre-induction cervical ripening there is no difference in efficacy between intracervical Foleys catheter and PGE_2 gel. Also factors like induction delivery interval, maternal and foetal outcome and need for further augmentation were similar in both the groups.

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