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Research Article

COMPARATIVE STUDY OF INTRA-CERVICAL FOLEY'S CATHETER AND PGE_2 GEL FOR PRE-INDUCTION RIPENING

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ABSTRACT
The success of induction of labor depends on the cervical status at the time of induction. For effective cervical ripening both Foley's catheter and PGE_2 gel were used. The aim of this study was to compare the efficacy of intra cervical Foley's catheter and intra cervical PGE_2 gel in cervical ripening for the successful induction of labor.
A randomized, prospective study was conducted in the Dept of OBGY, mvj mc and rh Bangalore from August 2007–August 2012. 400 patients at term with a Bishop's score ≤3 with various indications for induction were randomly allocated to receive (200 pts) intra-cervical Foley's catheter or PGE_2 gel (200 pts). After 6 h post induction, Bishop's score was noted labor was augmented if required. Statistical analysis was done using Chi square test and *t* test.
The groups were comparable with respect to maternal age, gestation age, indication of induction and initial Bishop's score. Both the groups showed significant change in the Bishop's score, 5.56 ± 1.89 and 5.49 ± 1.82 for Foley's catheter and PGE_2 gel, respectively, $P < 0.001$; However there was no significant difference between the two groups. There was no significant difference in the side effects. Twenty eight cesarean sections (14%) were performed in Group A and 37 (18.5%) were performed in Group B (not significant). The induction to delivery interval was 15.32 ± 5.24 h in Group A and 14.2 ± 5.14 h in Group B ($P = 0.291$). Apgar scores, birth weights and NICU admissions showed no difference between the two groups. This study shows that both Foley's Catheter and PGE_2 gel are equally effective in pre induction cervical ripening.

Key Words: *Cervical Ripening, PGE_2, Foley's Catheter*

INTRODUCTION
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 (National Institute for Clinical Excellence, 2001). The success of labor induction depends on the cervical status at the time of induction. It is generally predicted that the patients with a poor Bishop's score ≤3 have unacceptably higher rates of failure of induction (St.Onge and Conners, 1995). It was also shown that a low Bishop's score is associated with increased rates of cesarean sections, maternal fever and fetal asphyxia (National Institute for Clinical Excellence, 2001; St.Onge and Conners, 1995). To decrease the induction failure, cervical ripening by any methods is the answer.
The purpose of this study was to compare the efficacy of intra-cervical Foley's catheter with PGE_2 gel for pre-induction cervical ripening. The induction delivery interval, maternal and fetal outcomes and the need for augmentation of labor in or these two groups were also compared.

MATERIALS AND METHODS
The study was conducted at MVJ MC RH, BANGALORE in the Department of OBG from AUG2007 to AUG 2012. Ethical committee approval was taken in June 2007. The study population

(n = 400) was a mixture of high and low risk population. Patients at term with various indications for induction of labor were included in the study after a written, valid consent.

Inclusion Criteria

- Primigravida
- ≥37 weeks of gestation
- Singleton pregnancy
- Cephalic presentation
- Bishops score ≤ 3
- Intact membranes

Exclusion Criteria

- Multiple pregnancy
- Mal-presentation
- Absent membranes
- APH
- Medical disease e.g., heart disease, renal disease.

The patients were randomly allocated to either Foley's catheter (Group A, n = 200), PGE_2 gel (Group B, n = 200) method. 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 was noted.

Dose repetition of PGE_2 gel was considered if post-induction Bishop's score was ≤6 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.

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% (power of test 80%).

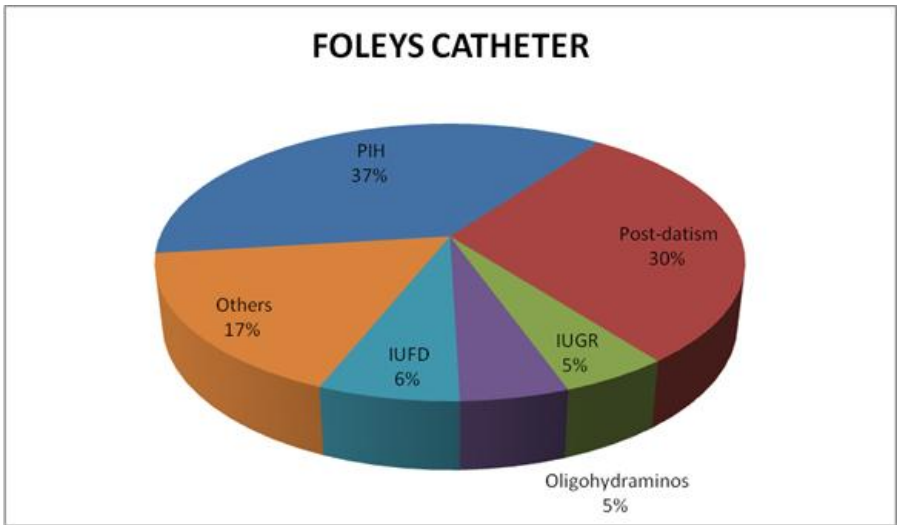
RESULTS

Group A and Group B had 200 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 (Tables 1, 2).

Table 1: Demographic profile

Variable	Group A (*n* = 200)	Group B (*n* = 200)	*P*
Maternal age	22.27 ± 2.97	22.00 ± 2.79	0.079
Gestation age	38. 7 ± 1.73	38.9 ± 1.68	0.11
Indication for induction			
PIH	74 (37%)	73 (36.5%)	
Post-datism	59 (29.5%)	62 (31%)	
IUGR	10 (5%)	11 (5.5%)	
Oligohydraminos	10 (5%)	01 (0.5%)	
IUFD	13 (6.5%)	17 (8.5%)	
Others	34 (17%)	36 (19%)	
Mean pre-induction score	1.48 ± 0.67	1.59 ± 0.78	>0.005

No statistically significant difference was demonstrated between the two groups Indication for induction



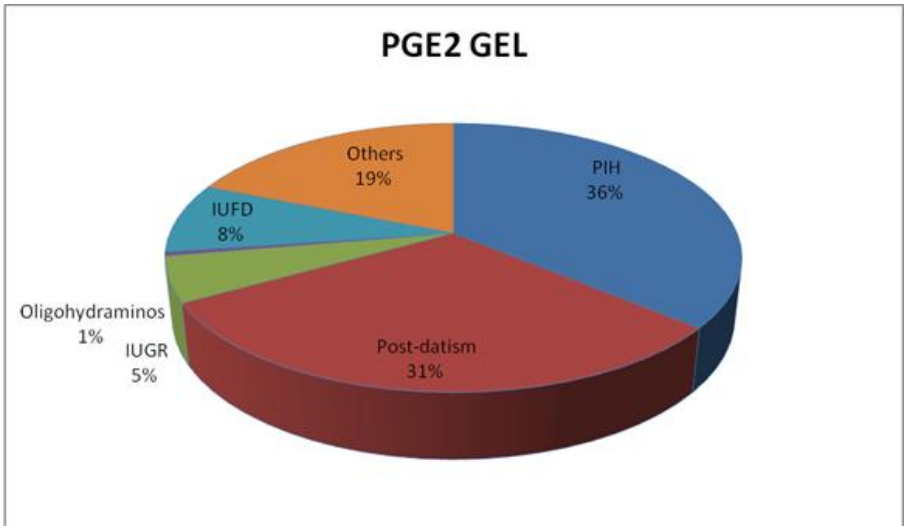
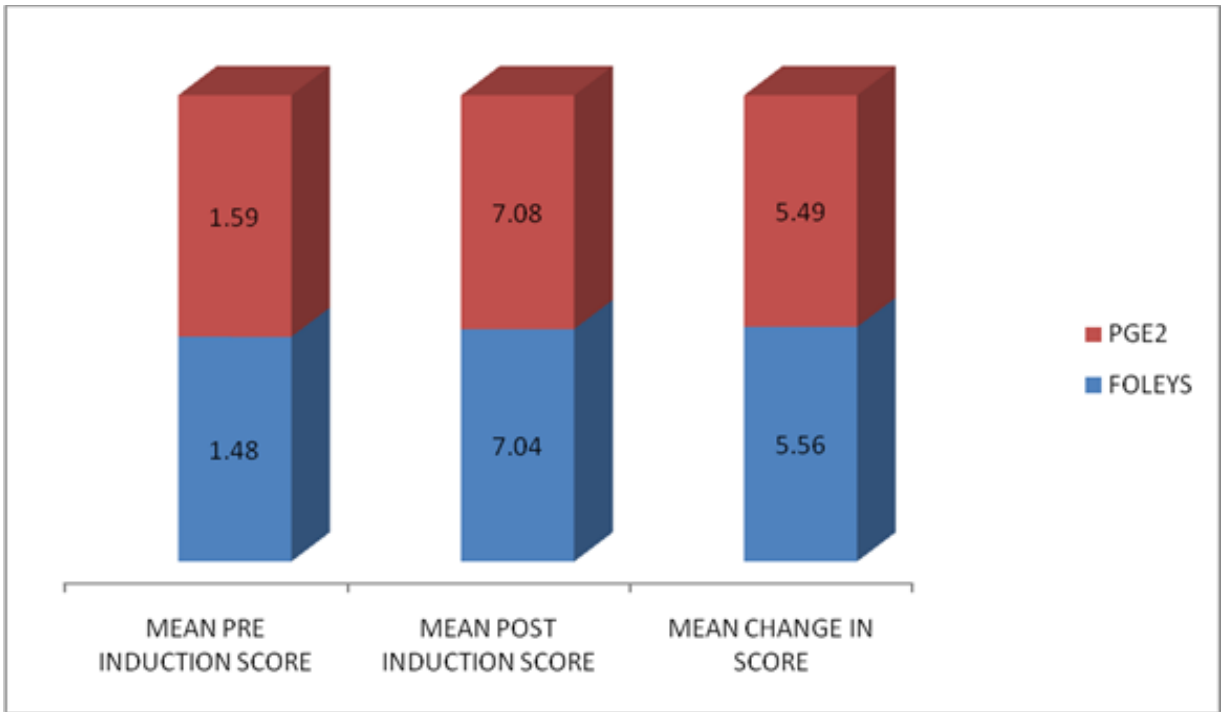


Table 2: Change in Bishop Score

Bishops score	**Group A (*n* = 200)**	**Group B (*n* = 200)**
Mean pre-induction score	1.48 ± 0.67	1.59 ± 0.78
Mean post-induction score	7.04 ± 1.72	7.08 ± 1.87
Mean change in score	5.56 ± 1.89	5.49 ± 1.82
	$t = 20.91$	$t = 40.17$
	$P < 0.0001$	$P \leq 0.0001$



In this present study improvement in the Bishop's score in Group A was 5.56 ± 1.89 (mean ± SD, $P < 0.001$) and in Group B it was 5.49 ± 1.82 (mean ± SD, $P < 0.001$); however no significant difference in the mean changes in the two groups could be established (Table 3).

Table 3: Need for augmentation

Mode of delivery	Group A (*n* = 200)	Group B (*n* = 200)	*P* value χ^2 test
Spontaneous	50 (25%)	58 (29%)	$\chi^2 = 4.45$
ARM	16 (8%)	20 (10%)	df^3
Oxytocin	74 (37%)	80 (40%)	$P = 0.21$
ARM + oxytocin	60 (30%)	42 (21%)	
Total	200	200	400

No significant difference in need for augmentation in both groups

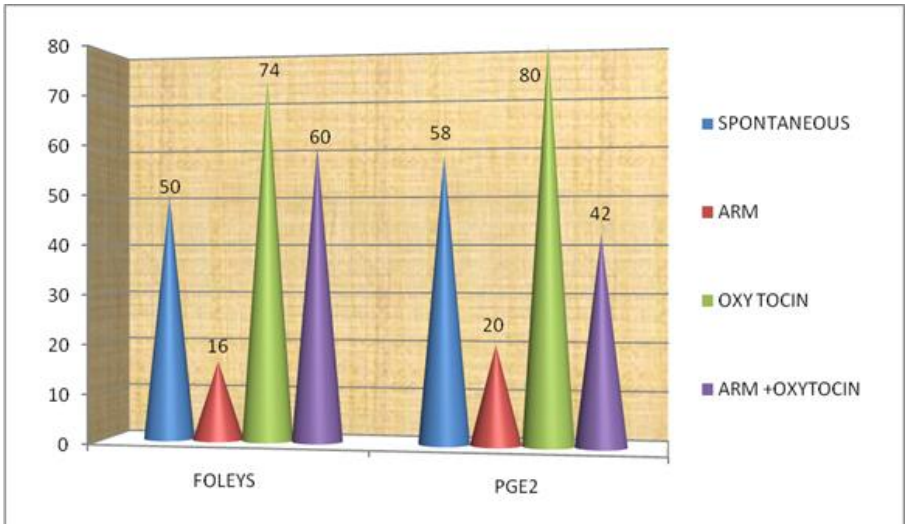
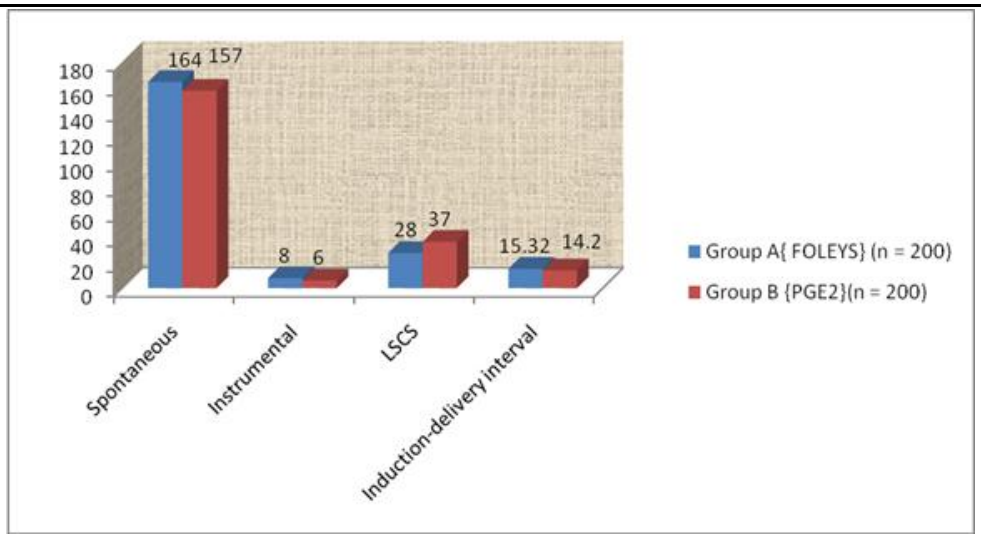


Table 4: Mode of delivery and induction-delivery interval

Variable	Group A (*n* = 200)	Group B (*n* = 200)	*P* value
Spontaneous	164 (82%)	157 (78.5%)	$\chi^2 = 1.68$
Instrumental	8 (4%)	6 (3%)	df^2
LSCS	28 (14%)	37 (18.5%)	$P = 0.438$
Total	200	200	
Induction-delivery interval	15.32 ± 5.24	14.2 ± 5.14	$t = 1.059$ $P = 0.291$



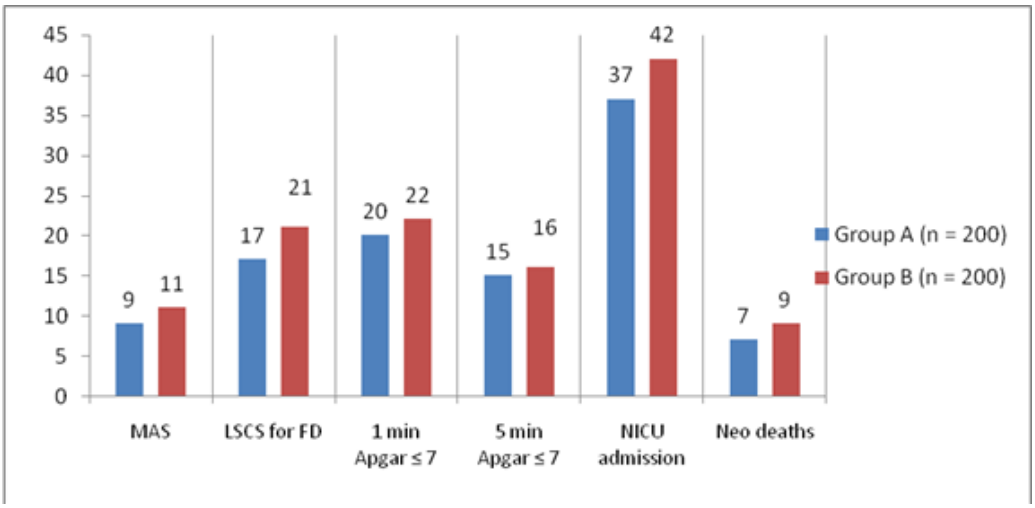
The need for further augmentation of labor was studied in this study. Spontaneous labor ensued in 50 patients in Group A (25%) compared with 58 patients in Group B (29%). In Foley's catheter group, need for augmentation of labor was required by doing ARM (n = 16) oxytocin infusion (n = 74) and both ARM + oxytocin 60 patients required.

In PGE_2 gel group, 20 patients required ARM, 80 patients required oxytocin and 42 patients required both ARM + oxytocin. There was no significant difference in need for augmentation in both groups.

Table 4 shows no significant statistical difference in spontaneous vaginal delivery in both the groups. Group A had 82% (n = 164) spontaneous deliveries whereas Group B had 78.5% (n = 157) spontaneous deliveries.

Table 5: Neonatal outcome

Variable	Group A (n = 200)	Group B (n = 200)	P value
MAS	9	11	>0.005 (NS)
LSCS for FD	17	21	
1 min Apgar ≤ 7	20	22	
5 min Apgar ≤ 7	15	16	
NICU admission	37	42	
No deaths	7	9	



Mode of delivery and induction-delivery interval

The need for operative intervention (LSCS) was also not significant in both the groups. LSCS was done for fetal distress in Group A for 17 cases and in Group B for 21 cases. The other indications for LSCS being failure to progress (10 and 13 respectively and failure of induction (1 and 3 respectively).

Table 5 shows the incidence of perinatal asphyxia with Apgar score ≤7 at 5 min and meconium aspiration syndrome was similar in both the groups. The neonatal birth weights were also comparable in both the groups (2.47 ± 0.44 in Group A and 2.58 ± 0.48 in Group B). 18.5% of babies in Group A (n = 37) and 21% of babies in Group B (n = 42) got admitted in NICU. However the morbidity in both the groups was not statistically significant.

DISCUSSION

The results of this study confirm that both Foley's catheter and PGE_2 gel are equally effective in pre-induction cervical ripening. The mean change in Bishops score in Foleys catheter 5.56 ± 1.89 (P < 0.0001) and PGE_2 gel 5.49 ± 1.82 (P < 0.0001) were highly significant. However, a comparison between the groups revealed that one method did not confer a statistically significant advantage over the other. There have been theoretic concerns regarding the introduction of infection with the use of Foley's

catheter. In this study there was no infectious morbidity. Similar were the observation of St.Onge and Conners (National Institute for Clinical Excellence, 2001) and Anthony *et al.*, (1999).

The need for oxytocin induced augmentation of labor was 37% in Group A and 40% in Group B. This is in agreement with studies done by Dewan *et al*., (2001).

The induction delivery interval showed no significant difference in the two groups. The mean I-D internal was 15.32 h in Foley's group and 14.2 h in PGE_2 group. Similar observations were observed by Dewan *et al.*, (2001).

The rate of LSCS in Group A was 14 and 18.5% in Group B ($P = 0.438$, NS). The most common indication for LSCS in Group A was fetal distress. Group A had 17 cases for FD and Group B had 21 cases of FD. The rate of LSCS in our study is agreeable (St.Onge and Conners, 1995; Anthony *et al.*, 1999). There was no association of increased rate of cesarean section with the Foley's catheter PGE_2 gel use.

Fetal outcome data showed no significant difference between Group A and Group B with respect to birth wt (2.47 ± 0.44 and 2.58, $\chi^2 = 4.28$, 3df, $P = 0.188$), MAS (9 and 11 respectively), 1 min Apgar score <7 (15 and 16 respectively), NICU admission rate (37 and 41 respectively). Thus the present study shows that the fetal outcome results were also comparable in both the groups. The total cost of Foley's catheter was much less than PGE_2 (Dewan *et al.*, 2001 and Anthony *et al.*, 1999).

Conclusion

In conclusion this study has shown that for pre-induction cervical ripening there is no difference in efficacy between intra cervical PGE_2 gel and intra cervical Foley's catheter. Also, other factors like induction-delivery interval, maternal and neonatal outcome and need for oxytocin for further augmentation were similar in both the groups.

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