

Comparative Study of Intra-cervical Foley's Catheter and PGE₂ Gel for Pre-induction Ripening (Cervical)

Deshmukh V. L. · Yelikar K. A. · Deshmukh A. B.

Received: 8 October 2008 / Accepted: 21 June 2011 / Published online: 22 September 2011
© Federation of Obstetrics and Gynaecological Societies of India (FOGSI) 2011

Abstract

Aim The success of induction of labor depends on the cervical status at the time of induction.

Objective For effective cervical ripening both Foley's catheter and PGE₂ gel are used. The aim of this study was to compare the efficacy of intra cervical Foley's catheter and intra cervical PGE₂ gel in cervical ripening for the successful induction of labor.

Study Design A randomized, prospective study was conducted in the Dept of OBGY, GMCH, Aurangabad from July 2005–January 2008. 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 PGE₂ 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.

Result 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 PGE₂ 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. **Conclusion** This study shows that both Foley's Catheter and PGE₂ gel are equally effective in pre induction cervical ripening.

Keywords Cervical ripening · PGE₂ · 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 [1]. 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 [2]. It was also shown that a low Bishop's score is associated with increased rates of cesarean sections, maternal fever and fetal asphyxia [1, 2]. To decrease the induction failure, cervical ripening by any methods is the answer.

Deshmukh V. L. (✉) · Yelikar K. A. · Deshmukh A. B.
Department of OBGY, GMCH, 120, Samarthnagar,
Aurangabad, India
e-mail: vldeshmukh@yahoo.co.in

The purpose of this study was to compare the efficacy of intra-cervical Foley's catheter with PGE₂ 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.

Material and Methods

The study was conducted at GMCH, Aurangabad in the Department of OBGY from July 2005 to January 2008. Ethical committee approval was taken in June 2003. 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, $n = 200$), PGE₂ 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 fetomaternal outcome was noted.

Dose repetition of PGE₂ 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 group. 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).

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

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 PGE₂ 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

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			
P/H	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

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
	$t = 20.91$	$t = 40.17$
	$P < 0.0001$	$P \leq 0.0001$

had 82% ($n = 164$) spontaneous deliveries whereas Group B had 78.5% ($n = 157$) spontaneous deliveries.

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 were 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.

Table 3 Need for augmentation

Mode of delivery	Group A ($n = 200$)	Group B ($n = 200$)	<i>P</i> 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 ($n = 200$)	<i>P</i> 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	$t = 1.059$ $P = 0.291$

Table 5 Neonatal outcome

Variable	Group A ($n = 200$)	Group B ($n = 200$)	<i>P</i> 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	
Neo deaths	7	9	

Discussion

The results of this study confirm that both Foley's catheter and PGE₂ 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 PGE₂ 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 Connors [2] and Anthony et al. [4].

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. [3].

The induction delivery interval showed no significant difference in the two groups. The mean I-D interval was 15.32 h in Foley's group and 14.2 h in PGE₂ group. Similar observations were observed by Dewan et al. [3].

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 [2, 4]. There was no association of increased rate of cesarean section with the Foley's catheter PGE₂ 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 PGE₂ [3, 4].

Conclusion

In conclusion this study has shown that for pre-induction cervical ripening there is no difference in efficacy between intra cervical PGE₂ gel or 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.

References

1. National Institute for Clinical Excellence. Clinical guidelines for induction of labour, Appendix-E. London: NICE; 2001.

2. St. Onge RD, Conners GT. Preinduction cervical ripening: a comparison of intracervical PGE₂ gel vs. the Foley catheter. *Am J Obstet Gynecol.* 1995;172:687–90.
3. Dewan F, Ara AM, Begum A. Foley's catheter versus prostaglandin for induction of labour. *Singap J Obstet Gynaecol.* 2001;32:56–63.
4. Anthony C, Sciscione DO, Helen M, et al. A prospective, randomized comparison of Foley catheter insertion vs. intracervical PGE₂ gel for preinduction cervical ripening. *Am J Obstet Gynecol.* 1999;180:55–9.