

COMPARATIVE STUDY OF EXTRA AMNIOTIC FOLEYS CATHETER AND INTRACERVICAL PGE₂ GEL FOR PRE-LABOUR CERVICAL RIPENING

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ABSTRACT: AIM: The aim of this study was to compare the efficacy of extra amniotic Foleys 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, KIMS, Karad from May 2012 to May 2014. 140 patients at term with a Bishop's score <6 with various indications for induction were randomly allocated to receive (70 pts) extra amniotic Foleys catheter or PGE₂ gel (70 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 compared with respect to maternal age, gestation age, indication of induction and initial Bishop's score. Both the groups showed no significant change in the Bishop's score for primigravida cases (P value-0.6) but for multigravida cases increment in Bishop's score was significantly more for PGE₂ group (P value-0.048). There was no significant difference in the side effects For primigravida cases there was no significant difference in cesarean section rate for both groups but in multigravida cases cesarean section rate significantly more in Foleys group (P value-0.049). There was no significant difference in the induction to delivery interval in both groups for primigravida cases, but for multigravida cases duration was significantly less in PGE₂ group (P value-0.047). APGAR scores and NICU admissions showed no difference between the two groups. Cost of induction was significantly less for Foleys catheter than PGE₂ gel. **CONCLUSION:** This study shows that both Foleys Catheter and PGE₂ gel were equally effective in pre induction cervical ripening in primigravida cases but for multigravida cases PGE₂ gel was more effective than Foleys catheter for pre induction cervical ripening.

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

The purpose of this study was to compare the efficacy of extra amniotic Foleys 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.

OBJECTIVES:

- To study and compare the improvement in pre-ripening Bishop's score in both the groups.
- To study induction- delivery interval in both groups.

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- To study the requirement of drugs for augmentation after induction of labour.
- To study the mode of delivery in both groups.
- To study maternal morbidity, neonatal morbidity and mortality in both groups.
- To study cost effectiveness of the methods.

MATERIALS AND METHODS:

STUDY DESIGN: Prospective, comparative study

SAMPLE SIZE: Total 140 cases;

GROUP-A: 70 CASES

GROUP-B: 70 CASES

STUDY PERIOD: May 2012 to May 2014.

PROCEDURE:

- 140 pregnant women after 37 completed weeks of gestation who needed induction and fulfilling the criteria of inclusion and exclusion were randomly allocated in to two groups: Group A & Group B.
- GROUP A: Induction with extra amniotic Foleys catheter.
- GROUP B: Induction with Prostaglandin E₂ gel.
- Detailed history and examination was done. Pre & post induction NST was taken.
- Pre induction Bishop's score was assessed and improvement in bishop score was assessed after 12 hours of induction.
- Demographic profile, gestational age, improvement of Bishop's score, induction- delivery duration, mode of delivery and feto-maternal outcome was noted.
- Dose repetition of PGE₂ gel was considered if post induction Bishop's score was <6 in both groups.
- Need of augmentation of labour was assessed and implemented by oxytocin administration.
- Failure of induction was declared if patient failed to go in active phase of labour within 24 hrs of induction.
- Student t test and chi square test were used to statistically compare the two groups.

INCLUSION CRITERIA:

- After 37 completed weeks of gestation who needed induction.
- Singleton pregnancy.
- Cephalic presentation.
- Bishop's score <6.

EXCLUSION CRITERIA:

- Multiple pregnancy.
- Malpresentation.
- Absent membranes.
- Antepartum haemorrhage.
- Medical disease like heart disease or renal disease, asthma, and liver diseases.

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- Local Infections –vaginitis, chorioamnionitis.
- Previous uterine scar.

OBSERVATIONS AND RESULTS: Among the 140 patients selected for the study, 70 patients were selected for Foleys catheter and 70 patients for PGE₂ gel.

The patient's characteristics like age and gravidity were comparable in both groups.

In both groups cases of primi gravida has maximum percentage than multi gravida cases. In GROUP-A 47 cases were primigravida and 23 cases were multigravida, In GROUP-B 51 cases were primigravida and 19 cases were multigravida.

Mean age in GROUP-A was 23.48 ± 2.92 yrs. and for GROUP-B was 23.18 ± 3.20 yrs.

Mean gestational age for GROUP-A was 40.06 ± 1.15 wks. And that for GROUP-B was 40.05 ± 1.14 wks.

INDICATION	GROUP-A		GROUP-B	
	number	percentage	number	percentage
postdated	46	65.71 %	44	62.85 %
PIH	17	24.28 %	19	27.14 %
IUD	0	0 %	2	02.85 %
IUGR	4	05.71 %	5	07.14 %
oligohydromnios	21	30 %	19	27.14 %
polyhydromnios	3	04.28 %	6	08.57 %
Total	70 cases		70 cases	

Table 1: Indication for induction

This table summarizes the indications of induction in both the groups. More common indications in both the groups were Post-dated, Pregnancy induced hypertension (PIH) and oligohydromnios.

BISHOP'S SCORE	GROUP-A	GROUP-B	P-VALUE
	47-cases	51-cases	
pre-induction	1.89 ± 1.73	1.76 ± 1.39	0.684
post-induction	7.17 ± 2.01	6.78 ± 2.91	0.451
increment	5.27 ± 2.28	5.01 ± 2.53	0.600

Table 2: Increment of Bishop's score in primigravida cases

Increment of Bishop's score in GROUP-A was 5.27 ± 2.28 and that of GROUP-B is 5.01 ± 2.53 . So the P-value was 0.600 means there was no significant difference between them. Change in Bishop's score same after induction for both groups.

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BISHOP'S SCORE	GROUP-A	GROUP-B	P-VALUE*
	23-cases	19-cases	
pre-induction	2.08 ± 1.34	2.42 ± 1.74	0.487
post-induction	7.08 ± 2.74	9.36 ± 3.43	0.021
increment	5 ± 3.07	6.94 ± 3.09	0.048

Table 3: Increment of Bishop's score in multigravida cases

Increment of Bishop's score in GROUP-A was 5 ± 3.07 and that of GROUP-B was 6.94 ± 3.09 . So the P-value was 0.048 means there was significant difference between them. Increment in Bishop's score was more in GROUP-B as compare to GROUP-A.

DRUG	GROUP-A		GROUP-B	
	47-cases		51-cases	
	Number	Percentage	Number	Percentage
oxytocin	28	59.57 %	13	25.49 %
PGE ₂ gel	-	-	19	37.25 %

Table 4: Any other drug used for augmentation in primigravida cases

In primigravida cases of GROUP-A significantly more number of patients needed oxytocin for augmentation as compared to GROUP-B (P value-0.0013).

DRUG	GROUP-A		GROUP-B	
	23-cases		19-cases	
	Number	Percentage	Number	Percentage
oxytocin	13	56.52 %	3	15.78 %
PGE ₂ gel	-	-	0	0 %

Table 5: Any other drug used for augmentation in multigravida cases

In multigravida cases of GROUP-B need for augmentation is significantly less as compared to GROUP-A (P value-0.017).

	GROUP-A	GROUP-B	P-VALUE
	47-cases	51-cases	
Induction-Delivery duration	20.95 ± 12.48 HRS.	22.60 ± 15.95 HRS.	0.572

Table 6: Induction-delivery duration in primigravida cases

The P-value was 0.572 means there was no statistically significant difference between two groups.

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	GROUP-A	GROUP-B	P-VALUE
	23-cases	19-cases	
Induction-Delivery duration	17.52 ± 9.62 HRS.	11.73 ± 8.47 HRS.	0.047

Table 7: Induction-delivery duration in multigravida cases

The P-value was 0.047 means there was statistically significant difference between two group.

MODE OF DELIVERY	GROUP-A		GROUP-B		P VALUE
	number	percentage	number	percentage	
Vaginal delivery	27	57.44 %	28	54.90 %	0.960
Instrumental delivery	0	0 %	0	0 %	-
LSCS	20	42.55 %	23	45.09 %	0.962
Total	47 cases		51 cases		

Table 8: Mode of delivery in primigravida cases

There was no significant difference in cesarean section rate for primigravida cases in both groups (P value-0.962).

MODE OF DELIVERY	GROUP-A		GROUP-B		P VALUE*
	number	percentage	number	percentage	
Vaginal delivery	17	73.91 %	18	94.73 %	0.165
Instrumental delivery	0	0 %	1	05.26 %	0.452
LSCS	6	26.08 %	0	0 %	0.049
Total	23 cases		19 cases		

Table 9: Mode of delivery in multigravida cases.

LSCS rate was significantly more in GROUP-A as compared to GROUP-B in multigravida cases (P value-0.049).

INDICATION FOR LSCS	GROUP-A		GROUP-B		P VALUE
	number	percentage	number	percentage	
Foetal distress	7	26.92 %	6	26.08 %	1.00
Failure of induction	3	11.53 %	10	43.47 %	0.026
Non progress	14	53.84 %	7	30.43 %	0.17
Request for LSCS	2	07.69 %	1	04.34 %	1.00
Total	26 cases		23 cases		

Table 10: Indications for LSCS

So in GROUP-A majority of patients having non-progress of labour as indication for cesarean section with no statistically significant difference (P-value is 0.17). And in GROUP-B majority of patients having failure of induction as indication for cesarean section with statistically significant difference (P value is 0.026).

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MATERNAL COMPLICATIONS	GROUP-A	GROUP-B	P- VALUE
Nausea	3	9	0.12
Vomiting	2	6	0.27
Hypertonus	0	4	0.11
Infection	1	2	1.00
Uterine rupture	0	0	-
APH	0	0	-
PPH	1	1	-
No complications	64	52	0.01

Table 11: Maternal complications

The overall incidence of complications has significant difference (P- 0.01). The incidence of complications was significantly more in GROUP-B as compared to GROUP-A.

COMPLICATIONS	GROUP-A	GROUP-B	P-VALUE*
Respiratory distress	1	1	-
IUD	0	0	-
Birth asphyxia	0	1	1.00
NICU Admission	4	5	1.00
No complication	66	63	0.53

Table 12: Foetal complications

In both the groups there was no statistically significant difference in the incidence of foetal complications (P-value is 0.53).

APGAR SCORE	GROUP-A	GROUP-B	P-VALUE*
AT 1 MINUTE	6.85 ± 0.54	6.52 ± 1.50	0.087
AT 5 MINUTE	8.87 ± 0.47	8.47 ± 1.86	0.084

Table 13: APGAR score

So in both groups there was no difference in APGAR score.

	GROUP-A	GROUP-B	P-VALUE*
AVERAGE COST	115 RS.	343.20 RS.	< 0.0001

Table 14: Cost of induction

So the cost of induction in GROUP-A was significantly less as compared to GROUP-B.

DISCUSSION: In this study, 140 patients were selected by simple randomization, with 70 patients in each group.

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In our study the mean increment in Bishop's score after induction in primigravida cases in Foleys catheter group was 5.27 ± 2.28 and in PGE₂ group was 5.01 ± 2.53 . The P value was 0.600 means there was no significant difference between two groups and the increment in Bishop's score was same for both groups (Table no.2). In multigravida cases in Foleys group the increment was 5 ± 3.07 and in PGE₂ group was 6.94 ± 3.09 . The P value was 0.048 means there was significant difference between two groups, so increment in Bishop's score for multigravida cases in Prostaglandin group was significantly more as compared to Foleys catheter group (Table no. 3).

In the study done by Tahir Jabbar et al¹ (2011) there was no significant difference in the increment of Bishop's score in two groups with P value 0.42.

In our study for primigravida cases in GROUP-A 59.57% cases required oxytocin augmentation, in GROUP-B 25.49% required oxytocin augmentation, P value was 0.0013 means oxytocin requirement was significantly more in Foleys group as compared to PGE₂ group (Table no.4). In multigravida cases in GROUP-A 56.52% cases required oxytocin, in GROUP-B 15.78% cases required oxytocin. The P value was 0.017 means oxytocin requirement was significantly more in Foleys group as compare to PGE₂ group. (Table no.5).

In the study done by Azra Naseem et al² (2007) they found that the requirement of oxytocin in Foleys group was 98% and that of PGE₂ group was 84%. P value was 0.014 means there was significant difference between two groups. But in the study done by Sujata et al³ (2012) in Foleys group oxytocin required in 30% cases and in PGE₂ group 17 % cases required oxytocin augmentation with P-value 0.16 means there was no significant difference between two groups.

In our study in primigravida cases the mean Induction to delivery duration for Foleys group was 20.95 ± 12.48 hrs. And that for PGE₂ group was 22.60 ± 15.95 hrs. The P value was 0.572 means there was no significant difference between them (Table no.6). In multigravida cases the mean induction to delivery duration for Foleys group was 17.52 ± 9.62 hrs. And that for PGE₂ group was 11.73 ± 8.47 hrs. The P value was 0.047 means there was significant difference between them (Table no.7).

In the study done by Marta Jozwiak et al⁴, they found that induction to delivery duration in PGE₂ group was significantly less as compared to Foleys group, P value was 0.0001. But in the study done by Azra Naseem et al² they found that the induction to delivery duration was significantly less in Foleys group as compared to PGE₂ group with P value 0.008. However in the study done by Deshmukh et al⁵ they found that no significant difference between both groups for induction to delivery duration with P value 0.291.

In our study in cases of primigravida the cesarean section rate for Foleys group was 42.55% and that for PGE₂ group was 45.09 %. P-value was 0.960 means there was no significant difference between two groups (Table no. 8). In cases of multigravida the cesarean section rate for Foleys group was 26.08 % and that for PGE₂ group was 0%. P-value is 0.049 means there was significant difference between two groups, so cesarean section rate was significantly less in PGE₂ group (Table no.9).

In the study done by Tahir Jabbar et al¹ they found that the cesarean section rate in Foleys group was 23.61 % and that of PGE₂ group was 21.33%, with P value 0.64 means there was no significant difference between them. Similarly in the study done by Dewan et al⁶ they found that there was no significant difference between two groups for LSCS rate with P value 0.614.

About the maternal complications in our study for Foleys group, we found that 3 cases had nausea, 2 cases had vomiting, 1 case had LSCS wound infection and 1 case had cervical tear at the

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time of delivery, in PGE₂ group we found 9 cases had nausea, 6 cases had vomiting, 4 cases had hypertonus, 2 cases had post LSCS wound infection and 1 case had cervical tear at the time of delivery (Table no.11). In the study done by Sujata et al³ they found that for Foleys group 10 % cases had discomfort at the time of insertion, for PGE₂ group 1% cases had tachysystole, 2% cases had hypertonus and 3% cases had discomfort at the time of insertion.

About the APGAR score at 1 minute and 5 minute in our study we did not find any significant difference between two groups (Table no.13). Also Deshmukh et al⁵ found no significant difference between two groups.

In our study we found about cost of induction that in Foleys group average cost was 115 Rs. and that for PGE₂ group was 343.20 Rs. and the difference was significant (Table no.14). Similarly Dewan et al⁶ found significant difference in induction cost, the cost for Foleys induction was significantly less as compare to PGE₂ group.

CONCLUSION: From our study we concluded that for primigravida cases Foleys catheter induction and PGE₂ gel induction both methods are effective in cervical ripening, safe, with minimal maternal and neonatal side effects. But in low socioeconomic group Foleys catheter induction is cost effective, safe method of induction. In multigravida cases Prostaglandin E₂ gel induction is more effective, simple, safe, with minimal maternal and neonatal side effects and with less cesarean section rate, with less need of augmentation as compared with Foleys catheter induction method. But where cost-factor is important in that case for multigravida also we can use Foleys catheter induction as it is low cost, safer, reversible method of induction. Also Foleys catheter insertion method is best option for cases where Prostaglandins are contraindicated.

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