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RESEARCH ARTICLE

A COMPARATIVE EVALUATION OF DINOPROSTONE GEL (PGE2) FOR CERVICAL RIPENING AND INDUCTION OF LABOR AT 8 HOURS Vs 12 HOURS INTERVAL IN A TERTIARY CARE CENTRE

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Abstract: ***AIMS:*** To study the difference in induction delivery interval in 8 hourly vs 12hourly intracervical dinoprostone PGE2 gel dosage intervals forinduction of labor. To study maternal & fetal outcomes in patients induced withintracervical PGE2 gel at 8 hourly vs 12 hourly dosage intervals.***MATERIALS AND METHODS***: This comparative study was conducted on 100 patients requiring induction oflabor after meeting the required inclusion and exclusion criteria and obtaininginformed and written consent.50 patients were induced with intracervical PGE2 gel 8-hourly called "group A" and 50 patients were induced with intracervical PGE2 gel 12-hourlycalled "group B". ***RESULTS:*** The mode of delivery in both the groups were comparable with 64% vaginal deliveries in group A and 62% in group B. The overall mean induction deliveryinterval in group A was found to be much lower than group B. Although the rateof cesarean section was comparable in both the groups and fetal distress was themost common indication for cesarean section, the overall incidence of fetaldistress was higher in group A than group B and that of Non progress of labourwas observed more in group B. There was no statistically significant differencein maternal outcome in terms of pre-induction bishop score, mode of delivery,number of doses administered, oxytocin requirement, side effects ofprostaglandins, postpartum haemorrhage and neonatal outcome in terms ofAPGAR scores, neonatal sepsis, NICU admissions among both groups.***CONCLUSION*** Induction of labor with intracervical dinoprostone PGE2 gel at 8 hourlyintervals has better outcomes than 12 hourly intervals in context to decreasedinduction delivery time without affecting other maternal and neonatal outcomes

Keywords: Intracervical PGE2 gel, 8 hourly and 12 hourly intervals, mode of delivery,induction delivery intervals.

INTRODUCTION

Labor is characterized by painful and forceful uterine contractions that affect cervical dilatation and cause the foetus to descend through the birth canal into external world.[1]

Induction of labour is defined as an intervention intended for the artificial initiation of uterine contractions before their spontaneous onset at or beyond the age of viability with the sole aim of delivery of the fetoplacental unit where the benefit of pregnancy termination exceeds its prolongation. This should ideally result in birth of the baby through the vaginal route. [2-4]

Induction of labour is one of the most common interventions practised in modern obstetrics all over the world. Indication and method for induction of labour depend on clinical condition of mother and baby and needs the decision of clinician considering the clinical scenario, wishes of mother and family members after explaining the associated advantages and risks and responses. [2-5] Early labour induction may be done in high-risk cases where continuation of pregnancy outweighs the risks of the foetus being born early. Elective induction is planned ones when both mother and foetus are healthy at 39 weeks of pregnancy or on maternal request.

Induction of labour is done using various methods which are intended to initiate uterine contractions and progressive cervical dilatation to achieve vaginal delivery. Cervical ripening is the process which is brought by the use of pharmacological or other means to soften, efface, or dilate the cervix to increase the chance of a vaginal delivery. Before induction one must ensure that the gestational age and foetal lung maturity is confirmed.

Successful induction of labour is said when vaginal delivery takes place within 24-48 hours. [6]

Induction of labour using prostaglandins is the most commonly used method to commence labour. There are many types of prostaglandins used with different protocols for each of these methods of induction of labour. Prostaglandins are important mediators of uterine activity and play a very important role in the contraction of uterine smooth muscles and the bio-physical changes associated with cervical ripening. PGE2 gel when applied locally induces collagen breakdown, fluid absorption by stroma and cervical ripening for induction

of labour.

AIMS AND OBJECTIVES

1. To study the difference in induction delivery interval in 8 hourly vs 12 hourly intracervical PGE2 gel dosage intervals for induction of labor.
2. To study maternal & foetal outcome in patients induced with intracervical PGE2 gel at 8 hourly vs 12 hourly dosage intervals.
3. To compare the rate of caesarean section in 8 hourly vs 12 hourly intracervical PGE2 gel dosage intervals in induction of labor.
4. To compare the need for oxytocin augmentation in 8 hourly v/s 12 hourly groups.

Inclusion criteria:

1. Indication for labour induction.
2. Singleton pregnancy.
3. Gestational age is more than 37 weeks.
4. Vertex presentation.
5. Bishop score < 5

Exclusion criteria:

1. Known hypersensitivity to prostaglandins.
2. Placenta previa.
3. Suspected chorioamnionitis.
4. Parity of >3.
5. A previous caesarean delivery or a history of uterine surgery.
6. Previous attempted induction of labor for this pregnancy.
7. Cephalopelvic disproportion.
8. Multiple Pregnancy
9. PROM
10. Refusal by the patient.

MATERIALS AND METHODS

The present study is a randomised prospective study conducted at the Rajiv Gandhi institute of medical sciences, Adilabad

100 Antenatal patient requiring induction of labor were studied over a period of 24 months. All the patients were included after checking the inclusion/exclusion criteria for the study after obtaining written informed consent. All patients were subjected to a detailed history, and general physical, systematic and obstetric examination as per the proforma attached.

Patients were randomly allocated under group A or group B.

Group A patients (n =50) were induced with intracervical PGE2 gel at 8 hourly intervals to a maximum of 3 doses.

Group B patients (n =50) were induced with intracervical PGE2 gel at 12 hourly intervals to a maximum of 3 doses.

STATISTICAL ANALYSIS

The data was analysed by a specific statistical method applicable to the various sets of data. Data were described in terms of range; mean ± standard deviation (± SD), median, frequencies (number of cases) and relative frequencies (percentages) as appropriate. To determine whether the data were normally distributed, a Kolmogorov-Smirnov test was used. Comparison of quantitative variables between the study groups was done using student t test and the Mann-Whitney test for parametric and non-parametric data respectively. For comparing categorical data, Chi square ($\chi 2$) test was performed and fisher exact test was used when the expected frequency is less than 5. A probability value (p value) less than 0.05 was considered statistically significant.

DISCUSSION

DEMOGRAPHIC DISTRIBUTION

The age of patients in our study was in range of 20 to 40 years; the mean age of the patients was 25.50 ± 3.22 in group A and 26.14 ± 4.24 in group B which was comparable in both the groups. 65% of parturient were primigravida and 35% were multigravida. In both group A & B majority of patients were primigravida (66% and 64% respectively). Patients included in present study were all term pregnancies (>37 weeks)

INDICATION FOR INDUCTION

The most common indication for induction in our study was hypertensive disorders of pregnancy group (38% in group A and 34% in group B) followed by postdates (32% in group A and 32% in group B), oligohydramnios, intrahepatic cholestasis of pregnancy, IUGR and GDM which is similar to study conducted by Modi S et al [7] in which 66% of patients were in the category of Pregnancy induced hypertension.

In the study conducted by Rafiq-Ul-Islam [8], Fazia R et al [9], George M et al [10] and Bashutheen NS et al [11] the most common indication for induction was postdates followed by Gestational hypertension, IUGR and Oligohydramnios.

NUMBER OF DOSES

Requirement of 2nd or 3rd dose of PGE2 gel was decided after assessing Bishop score, uterine contractions and fetal monitoring. If the Bishop score was ≤ 5, inadequate uterine contractions with normal fetal heart rate pattern was observed, next dose of PGE2 gel was instilled. In the present study, 15.2% of women in group A required all three doses among primigravida. Whereas in group B, 28.1% of women required all three doses among primigravida. 60.6% of primigravida in group A and 59.4% of primigravida in group B required ≥ 2 doses, which infers more than half of the primigravida require either 2 or 3 doses irrespective of the time interval used. None of the multigravida required 3 doses in either of the groups. In the study conducted by Rafiq-Ul-Islam et al [8], Krithika KS et al [12] and Shanti C et al [13] second dose was given after 12 hours and in the study done by Fazia R et al [9] second dose was given between 6 to 12 hours. In the study conducted by George M et al [10] single doses were administered and outcomes were noted at 6, 12, 18 and 24 hours whereas in the study done by Menon M et al [14] and conventional method of 6 hourly

intervals was followed. None of these studies compared the difference in requirements of doses and outcome in relation to parity of the cases included.

REQUIREMENT OF OXYTOCIN FOR AUGMENTATION OF LABOUR

It was 68% in group A and 64% in group B in present study. The differences between both the groups were not significant. Similar results were observed by Rafiq-Ul-Islam et al [8] who used 12 hourly intervals of prostaglandin gel interval. Fazia R et al [9] used 6 to 12 hourly intervals between two doses, Menon M et al [14] used 6 hourly intervals of prostaglandin gel insertion but the requirement of oxytocin was similar in all cases. This suggests that need of oxytocin for further augmentation was not affected by PGE2 gel doses given for cervical ripening or induction of labor.

MODE OF DELIVERY

In the current study, 63% had a normal vaginal delivery and 37% underwent caesarean section. Fazia R et al [9], reported a vaginal delivery rate of 82% and Krithika KS et al [12] reported a vaginal delivery rate of 84% in their study. In a multicentric trial done by Noah ML et al [16] 83% had successful vaginal deliveries with intracervical PGE2 gel, which was significantly high vaginal delivery rate.

Higher incidence of caesarean section in our study may be attributed to more women of high-risk pregnancy included in our study and lower rates of instrumental delivery in our institute.

Primigravida in 8 hourly versus 12 hourly interval group: When the mode of delivery was compared between primigravida of both groups, caesarean section rate was higher in 12 hourly group (50%) as compared to 39.4% of primigravida in 8 hourly group (group A).

Multigravida in 8 hourly versus 12 hourly interval group: Vaginal delivery rate was higher in both the groups among multigravida (70.6% in group A Vs 83.3% in group B)

However, the difference was more marked among multigravida in group B when compared to primigravida in group B (83.3%in multigravida Vs 50% in primigravida) indicating a significantly higher vaginal delivery rate among multigravida in 12 hourly group.
When sub-group analysis was done among primigravida receiving ≥ 2 doses for mode of delivery, majority had vaginal delivery in both the groups (68% in group A and 57.14% in group B).

No significant difference was observed when overall caesarean section rate was compared in both the groups (18/50 in group A Vs 19/50 in group B).

Foetal distress (Pathological/non- reassuring CTG) was the most common indication for caesarean section among both the groups. However, it was significantly higher in 8 hourly group (83.3%) as compared to 12 hourly (47.4%)

Non progress of labor was encountered more in 12 hourly group (42.1%) as compared to 8 hourly group (5.6%) as indication for caesarean section.

In the study conducted by Rafiq-Ul-Islam et al [8], Fazia R et al [9], George M et al [10] and group -3 of Menon M et al [14] reported the percentage of caesarean sections performed in view of failed induction/Non progress of labor was 8%, 4%, 17.2% and 71%. Bashutheen NS et al [15] in their group 2 reported caesarean section for failed induction in 31.4% and non-progress of labor in 11.4%.

INDUCTION DELIVERY INTERVAL

Majority of patients in both the groups in present study, delivered vaginally in less than 24 hours. The overall mean induction delivery time is 17.31 ± 6.70.
Further, the sub-group comprising of the patients requiring ≥ 2 doses, the mean induction delivery interval in group A was 16.04 ± 4.82 and in group B was22.18 ± 6.87, which is significantly higher in group B and statistically also significant with p-value-0.004.

The mean induction delivery time interval for primigravida in both the groups was higher than that of multigravida. The difference between mean induction delivery interval was significantly higher in primigravida in 12 hourly group when compared with multigravida in same group. (23.33 ± 7.83 Vs 17.12 ± 3.95 hours)

In the study done by Bashutheen NS et al [15], the overall mean induction delivery interval overall was 16.43 hours, the mean induction delivery interval in primigravida was 20.6 hours and in multigravida was 10.8 hours, which is more in primigravida and similar in multigravida of the present study.

NEONATAL OUTCOME

In the present study, the mean APGAR score of both groups were similar and there was no statistically significant and difference in number of NICU admissions and neonatal sepsis in both the groups. Rafiq-Ul-Islam et al [8], Fazia R et al [9], George M et al [10] and Menon M et al [14] also found no difference in neonatal outcomes in their studies.

TABLE 1- THE DEMOGRAPHIC DATA OF GROUP A AND GROUP B

S.NO	DEMOGRAPHIC VARIABLES		GROUP A (n=50)	GROUP A %age	GROUP B (n=50)	GROUP B %age	TOTAL	P-VALUE
1	AGE	< 25 YEARS	25	50%	21	42%	46	0.179
		26-30 YEARS	22	44%	20	40%	42	
		> 30 YEARS	3	6%	9	18%	12	
2	RESIDENCE	RURAL	39	78%	43	86%	82	0.2978
		URBAN	11	22%	7	14%	18	
3	SOCIOECONOMIC STATUS	CLASS I	2	4%	3	6%	2	0.8848
		CLASS II	3	6%	3	6%	2	
		CLASS III	5	10%	7	14%	8	
		CLASS IV	40	80%	37	74%	38	
		CLASS V	0	0%	0	0%	0	
4	LITERACY	LITERATE	38	76%	32	64%	70	0.1904
		ILLITERATE	12	24%	18	36%	30	
5	OCCUPATION	EMPLOYED	8	16%	6	12%	14	0.5643
		UNEMPLOYED	42	84%	44	88%	86	
6	BMI Kg/m^2	18.5-22.9(NORMAL)	38	76%	40	80%	78	0.8036
		23-24.9(OVER WEIGHT)	10	20%	9	18%	19	
		>25 (OBESE)	2	4%	1	2%	3	
BMI		MEAN ± SD	23.7 ± 3.9		22.8 ± 3.6			0

The most common indication for induction of labor in the present study belonged to Hypertensive disorders of pregnancy (34/100) with 38% in group A and 34% in group B. Other indications for induction were Post-dated pregnancy 32% in each group, Oligohydramnios 14% in group A and 18% in group B, Gestational diabetes mellitus, Intrahepatic cholestasis of pregnancy and Intrauterine growth restriction. (TABLE 10) Both the groups were comparable in terms of indication for induction of labor (p- value > 0.05)

TABLE 2 - INDICATIONS FOR INDUCTION OF LABOR

INDICATION FOR INDUCTION		Group A (n=50)		Group B (n=50)		total	Chi -square value	p-value
		No. of cases	%age	No. of cases	%age			
Post dated	Post dated	16	32%	16	32%	32	1.138	0.888
GDM	GDM	1	2%	0	0%	1		
IHCP	IHCP	5	10%	6	12%	11		
Oligohydramnios	Oligohydramnios	7	14%	9	18%	16		
Oligohydramnios and IUGR	Oligohydramnios, IUGR	2	4%	4	8%	6		
Hypertensive disorders of pregnancy	Gest HTN	9	18%	8	16%	17		
	Eclampsia	1	2%	0	0%	1		
	pre-eclampsia	6	12%	6	12%	12		
	pre-eclampsia with oligohydramnios	2	4%	1	2%	3		
	pre-eclampsia with oligohydramnios with IUGR	1	2%	0	0%	1		

TABLE 3 - MODE OF DELIVERY

MODE OF DELIVERY	GROUP A (n=50)		GROUP B (n=50)		Total	Chisquare value	pvalue
	No. of cases	%age	No. of cases	%age			
LSCS	18	36%	19	38%	37	0.043	0.836
FTVD	32	64%	31	62%	63		
TOTAL	50	100%	50	100%	100		

From the above table (TABLE 15), In group A, 36% of women underwent caesarean section, 64% underwent normal vaginal delivery. In the group B, 38% of women underwent caesarean section, and 62% underwent normal vaginal delivery. Both groups had similar outcomes in terms of mode of delivery. (pvalue >0.05)

TABLE 4 - INDICATION FOR CESAREAN SECTION

Indication for caesarean section	GROUP A (n=18)		GROUP B (n=19)		Total	Chi-square value	pvalue
	No. of cases	%age	No. of cases	%age			
2nd stage arrest	2	11.11%	2	10.52%	4	7.0225	0.0711
Pathological/non-reassuring CTG	9	50%	6	31.57%	15		
Pathological/Non-reassuring with MSL	6	33.33%	3	15.78%	9		
NPOL	1	5.55%	8	42.10%	9		
Total	18	100%	19	100%	37		

In present study, there was no significant difference between Caesarean section rate in both groups (18/50 in group A Vs 19/50 in group B).

On comparing the indications for the caesarean section, it was observed that fetal distress (Pathological/Non-reassuring CTG) was most common indication for caesarean section in both groups however it was significantly higher in group A, 83.3% (15/18) as compared to group B, 47.4% (9/19). Non-progress of labor was more common indication in group B as compared to group A (42.1% Vs 5.6%)

TABLE 5 - INDUCTION TO DELIVERY INTERVAL RANGES BETWEEN GROUP A AND GROUP B

Induction-delivery interval	GROUP A (n=32)		GROUP B (n=31)		Total	Chi-square value	pvalue
	No. of cases	%age	No. of cases	%age			
< 24 hrs	31	96.87%	26	83.87%	57	3.0902	0.0787
24-48 hrs	1	3.12%	5	16.12%	6		
> 48 hrs	0	0%	0	0%	0		
Total	32	100%	31	100%	63		

Majority of patients delivered within 24 hours in both groups (96.87% in group A & 83.87% in group B) whereas only 3.12% of group A and 16.12% of group B delivered between 24-48 hours. However, the difference between Group A and group B was not significant statistically. (Table 21)

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