EVALUATION OF PROSTAGLANDIN E_2 INTRACERVICAL GEL FOR CERVICAL RIPENING AND ITS IMPACT ON LABOUR

P. R. HANDA ● S. B. BASU ● K. B. SINHA

SUMMARY

Prostaglandin E_2 intracervical gel was used for cervical ripening before induction of labour in 126 patients (94 primigravidae and 32 para 1 or above) with unfavourable cervix. Overall 73% patients went into labour and 50% delivered within 12 hrs of application of PG gel. In both the groups together, 85.7% patients had vaginal delivery and 14.3% underwent caesarean section. There was no perinatal loss but instances of uterine hypertonus, foetal bradycardia and birth asphyxia were recorded. PG gel induced labour in majority of patients (instead of mere cervical ripening) with shortened induction delivery interval. However, patients need close monitoring because of increased risk of foetal bradycardia. Incidence of caesarean section remained apparently unchanged.

INTRODUCTION

Cervical ripening is an important and very desirable prelude to induction of labour. Degree of cervical ripeness is directly proportional to the successful outcome of induced labour. Prostaglandins, both F_2 and E_2, have been used extensively for ripening of cervix at term. However, these agents were made freely available in India only recently and there is not enough experience with their use. This study was designed to test the efficacy and complications with the locally available PG intracervical gel (Cerviprime - Astra IDL).

Dept. of Obst. & Gyn. Tata Main Hospital, Jamshedpur.
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MATERIALS AND METHODS

Women admitted for induction of

labour at or near term in Tata Main Hospital, Jamshedpur, were recruited for study from Dec. '92 through May '93. Informed consent was taken from the patients after explaining the procedure.

Inclusion criteria

(1) There must be clear indication to terminate pregnancy; where its continuation is more hazardous than the proposed intervention.

(2) Duration of pregnancy is reasonably ascertained either by clinical examination in early pregnancy or by ultrasound dating before 20 weeks.

(3) No contraindication for trial of labour.

(4) Unfavourable cervical Bishop score of 4 or less (Bishop 1964)

Exclusion criteria

(1) Previous caesarean section

(2) Severe intrauterine growth retardation

(3) History of vaginal bleeding during pregnancy

(4) Ruptured membranes

(5) Severe vaginal / cervical infection

(6) History of asthma / serious drug hypersensitivity

Before enrollment each patient had baseline cervical Bishop score measured, a foetal non-stress test and, where indicated, a sonogram and biophysical profile done. After entry into study each patient was examined using a sterile speculum and under direct visualisation PGE_2 gel was instilled endocervically. Patient was kept in the labour room and monitored for any uterine contractions and foetal heart rate regularity for about 6 hrs and later transferred to the ward. After approximately 20 hrs patient was examined again and change in cervical findings recorded. If there was favourable and sufficient change in the cervical score, amniotomy was done followed by oxytocin infusion in escalating dosage, if required. If there was no significant change in the cervical score, another dose of PG gel was applied with the same follow-up as on previous day. Duration of labour and its outcome including Apgar score of newborns was recorded for all the cases. In the event of caesarean delivery, indication for operation and cervical dilatation and effacement just before the procedure was also recorded.

RESULTS

Data were analysed for 126 patients (94 primigravidae and 32 para 1 or above) who fulfilled all inclusion criteria and didnot drop-out during the course of study. Patients who were found to have cervical Bishop score of more than 4 at the time of instillation of PG gel were excluded from this analysis. One patient did not agree for repeat application of gel and two declined further oxytocin infusion. They too were excluded.

The commonest indication for induction of labour was hypertension (63.5%) followed by post term pregnancy (28.6%) as shown in Table I. Majority of the patients (73%) went into labour within 12 hrs of the application of PG gel (Table II). Only 16 (17%) primigravidae required repeat application of PG gel whereas none of the parous patients needed second application. Amniotomy at reassessment was done in 20 (21.9%) primigravidae and 4

(12.5%) parous patients. Oxytocin augmentation following amniotomy was required in 14 (14.9%) primigravidae and 4 (12.5%) parous patients. Overall, 85.7% (108) patients had vaginal delivery and 14.3% (18) underwent caesarean section.

Among vaginal deliveries 74.1% (80) patients delivered within 24 hrs of PG gel application. Time interval between PG gel application and onset of active labour was variable and in general labour was not allowed to prolong beyond 24 hrs (Table III). Out of 18 caesarean deliveries 8 operations were done for failure to progress; at least 2 for definite cephalo-pelvic disproportion (Table IV). Five patients underwent caesarean section because of meconium stained liquor at amniotomy. There was no other evidence of foetal jeopardy but oxytocin induction was avoided for different reasons. Foetal distress was an accompaniment in the remaining 5 caesarean deliveries.

Table I

Distribution of patients by indication for induction of labour

	Primi	Para 1 or above	Overall percentage
Total number of patients	94	32	100
Mild hypertension	46	12	46.1
Severe hypertension	12	2	11.1
Hypertension with mild IUGR	8	—	6.3
Mild IUGR alone	8	2	7.9
Post-term pregnancy (Gestation 41 weeks or above)	20	16	28.6

Table II

Distribution of patients by outcome of induction of labour

	Primi	Para 1 or above	Overall percentage
Total No. of Patients	94 (100)	32 (100)	126 (100)
Labour within 12 hrs of application of gel	64 (68)	28 (87.5)	92 (73)
Repeat application of gel	16 (17)	—	16 (12.7)
Amniotomy at reassessment (after 20-44 hrs)	20 (21.3)	4 (12.5)	24 (19.0)
Oxytocin augmentation of labour	14 (14.9)	4 (12.5)	18 (14.3)
Vaginal delivery	80 (85.0)	28 (87.5)	108 (85.7)
Caesarean delivery	14 (14.9)	4 (12.5)	18 (14.3)

Figures in parentheses indicate percentage

There was no perinatal death but few complications were recorded. Uterine hypertonus with foetal bradycardia was found in 6 patients out of which 4 delivered vaginally and 2 underwent caesarean section. Four newborns suffered mild and 2 suffered severe birth asphyxia. Postpartum haemorrhage was recorded in two patients.

Table V shows distribution of newborns by birth weight. Two growth retarded babies were less than 2 kg (1.9 kg each) and 30 weighed less than 2.5 kg each. Majority of newborns (69.9%) had birth weight between 2.5 and 3.49 kg and, 6 weighed more than 3.5 kg each.

Table III

Distribution of patients delivered vaginally

	Primi	Para 1 or above	Overall
Total No. of Patients	80 (100)	28 (100)	108 (100)
Delivered within 12 hrs of PG gel application	34 (42.5)	20 (71.4)	54 (50.0)
Delivered within 24 hrs of PG gel application	56 (70.0)	24 (85.7)	80 (74.1)
Delivered after 24 hrs of PG gel application	10 (12.5)	2 (7.1)	12 (11.1)
Delivered within 24 hrs of reassessment	6 (7.5)	2 (7.1)	8 (7.4)
Delivered after 24 hrs of reassessment	8 (10.0)	—	8 (7.4)

Figures in parentheses indicate percentage

Table IV

Distribution of patients by indication for caesarean section and complications

Indication for caesarean/Complication	No. of patients
Failure to progress/CPD/DTA*	8
Meconium stained liquor without other evidence of foetal distress	5
Maternal pyrexia with foetal tachycardia	2
Foetal distress	3
Uterine hypertonus with foetal bradycardia+	6
Mild birth asphyxia**	4
Severe birth asphyxia***	2
Postpartum haemorrhage	2

* One case each of documented cephalo-pelvic disproportion and deep transverse arrest

** One minute Apgar score 4-6

*** One minute Apgar score less than 4

\+ Four patietns delivered vaginally

Table V

Distribution of newborns by birth weight

Birth weight	No. of newborns	Percentage
Less than 2.0 kg	2	1.6
2 - 2.49 kg	30	23.8
2.5 - 2.99 kg	48	38.1
3 - 3.49 kg	20	31.7
More than 3.5 kg	6	4.8

DISCUSSION

Prostaglandin E_2 both in the form of vaginal tablet and intracervical gel has been found useful agent for induction of labour (Kennedy et al 1982; Ulmsten 1988) although gel may be slightly superior in clinical efficacy (Mahmood 1989). The present study also confirmed its utility for induction of labour. Since nearly three fourth of the patients went into labour, it is more of a method to induce labour than to ripen the cervix. This could partly be because of little higher placement of gel making it extra-amniotic and giving rise to generalised effect. Nevertheless this was remarkable response considering low cervical Bishop score in the primigravidae. Duration of labour was also shortened and 50% vaginal deliveries occurred within 12 hrs of gel application. Further, labour could be induced in all patients following PG gel application and there was no failure of induction of labour.

All caesareans do not reflect the failure of PG gel. High incidence of caesarean section was partly because of the nature of study group of patients. Without a comparable control group it is difficult to comment on the effect of PG gel on incidence of caesarean section.

After instillation of PG gel patients need more careful monitoring because of the possibility of uterine hypertonus and foetal bradycardia. In this study these complications were encountered. In one case of severe birth asphyxia foetal bradycardia was missed. There is possibility of other patients having had uterine hypertonus with or without transient foetal heart rate deceleration which was not detected and fortunately did not result in serious consequences.

On the whole PG gel was found as a useful and potent method of inducing labour but calls for a more close monitoring of patients in a fully equipped unit.

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