PRE-INDUCTION CERVICAL SOFTENING WITH ENDOCERVICAL PGE_2 gel.

AMARNATH BHIDE ● S. N. DAFTARY

SUMMARY

A randomized placebo controlled study was undertaken to evaluated the efficacy of a single application of PGE_2 gel 0.5 mg. (Cerviprime) endocervically in 34 patients and application of K-Y jelly in 34 controls. A comparison of labour outcome in the two groups revealed a significant increase in the Bishop Scores, Shorter Induction supplementary oxytocin stimulation, comparable maternal and Foetal outcomes and minimal side-effects.

INTRODUCTION

Spontaneous labour and vaginal delivery in uncomplicated parturition follow a cascade of synchronized events, which lead to "ripening of the cervix", and a progressive labour. If ripening fails to occur, it may be confidently predicted that the attempts at induction will be prolonged and occassionally even completely unsuccessful. (Prins R. P., Bolton RN, Mark C. et al 1983).

Although the role of prostaglandins (E_2 and F_2) in cervical ripening and labour induction are well known, the optimal administration route (intravenous, oral, oromucousal, extra-amiotic, intravaginal o intracervical) is still controversial. Howeve a number of reports have appeared i literature favouring the gynaecologica (intravaginal, intracervical) route, claimin not only the advantage of shorter medicatio delivery time, fewer side effects, but princi pally focussing on the one time dos response which makes its administratio simple and attractive and causes minima discomfort to the patients (Oury et al 1981

Various complications of pregnancy ma necessitate termination of pregnancy befo term, a time when the cervix is often u favourable and unripe. Since induction labour is predicted to be tardy and matern and foetal risks increased, hence obst tricians increasingly resort to caesarean se

Dept. of Obst. & Gyn.

Accepted for Publication on 23.04.1993.

tions.

Clinical Trials, (Yonekura et al 1985, Trofatter et al 1985) have established the efficacy of PGE_2 get intracervical application to be advantageous in terms of shorter labours and diminished side-effects.

The objective of this study was to determine in comparison to placebo application (K. Y. Jelly) the effect of a single intracervical dose of Prostaglandin E_2 gel on cervical ripening and the subsequent induction of labour and need for oxytocin. A comparison of maternal and foetal outcome was also made.

MATERIALS AND METHODS

Sixty-eight women with medical and/or obstetric indications for induction of labour were enrolled for the study.

Admission criteria included informed consent, gestational maturity exceeding 34 completed gestation weeks, or above. Bishop Score < 4 and parity upto three.

Exclusion criteria included, any previous attempt at induction, ruptured membranes, history of allergy or asthma, previous uterine surgery, suspected foetal compromise, history of vaginal bleeding and maternal age 35 years and above.

Patients were allocated alternately to the study (PGE_2 gel) and control (Placebo - K. Y. Jelly) groups.

Each patients was admitted to the delivery room, and after intracervical application of PGE_2 gel or placebo, close clinical monitoring of mother and foetus at 15.0 minute intervals for 1 hour was carried out. The Bishop Score was reviewed after 8 hours of drug application, thereafter if the patient had not progressed into spontaneous labour, an oxytocin drip was set up (5IU in 500 ml. 5% glucose @ 2 mU/min. stepping up the dose every 20 minutes) and maintained so as to obtain effective uterine contractions. At 3.0 cms. cervical dilatation, routine amniotomy was performed, and a partogram initiated. Drugs to control pain were administered according to the patients individual needs. At subsequent examinations the Bishop scores of patients who had gone into labour was considered as 10.

RESULTS

1. **Clinical Profile :** A comparison of the clinical profile of the patients included in the study is shown in Table I. The above table shows that the patients in the study and placebo group were comparable.

2. **Indications for Termination :** The indications for labour induction in the two groups is shown in Table II.

   It will be noted that post-datism, and obstetric causes predisposing to placental insufficiency comprised, the main indication for induction of labour.

3. **Bishop Scores :** The Bishop scores before and after application of drug in the two groups is shown in Table III. The above table shows that the bishop

Table I

Comparison of Clinical Profiles

Parameters	PGE_2 gel. N = 34	Placebo N = 34
1. Mean Age (yrs)	29.3	28.4
2. Weight (Kgs.)	56.2	54.2
3. Gestational age (wks)	38.2	37.4
4. Gravidity	1.76	1.82
5. Mean B.P.	124/80	116/76

Table II

Indications for Induction

Indication for Induction	PGE_2 Gel N = 34	Placebo N = 34
1. Postdatims (Term + 10 or more days)	16	17
2. P. I. H. / Pre-eclampsia	8	7
3. I. U. G. R.	5	7
4. Diminished Foetal movements with Bordeline NST	4	2
5. Controlled Gestational Diabetes	1	—
6. Previous unexplained still-birth	—	1

Table III

Comparison of Bishop Scores

	PGE_2 gel		Placebo	
	Before	8 hrs. after	Before	After
Primigravide	1.4 ± 1.1	7.2 ± 2.4	1.7 ± 1.2	2.3 ± 1.3
Multigravidae	2.8 ± 1.0	8.5 ± 3.4	2.5 ± 1.2	3.5 ± 1.2

Table IV

Progress of Labour

	PGE_2 Gel	Placebo
1. Spont onset of Labour	16	Nil
2. Oxytocin Administration required	18	34
3. Amniotomy	18	34
4. Ind. to Delivery interval. (vaginal Deliv. cases only)	16.4 hr.	28.3
5. Vaginal Deliv.	32	29
unassisted	22	18
Vacuum or for-ceps	10	11
6. C. Section	2	5

Table V

Foetal Outcome

		PGE_2 Gel	Placebo
1.	Foetal sex		
	Male	18	12
	Female	16	22
2.	Foetal Weight	3.250 kg. ± 650 gms.	3.350 kg. ± 550 gms.
3.	APGAR Scores		
	After 1 min.	7.8 ± 0.7	7.5 ± 1.1
	After 5 min.	8.4 ± 0.3	8.6 ± 0.5

scores remained almost unaffected in the placebo group. Whereas in the study group, there was a remarkable improvement, more so in multiparae.

4. Progress of labour in the two groups.

5. **Foetal Outcome :**

A comparison of the Foetal outcomes in the two groups showed, the following.

The foetal outcomes were comparable. There was no perinatal mortality in the series.

DISCUSSION

The ability of PGE_2 to facilitate and even initiate labour has been demonstrated repeatedly. (Ulmsten et al, Calder et al, Verma & Norman, 1984). It's action involves both local "ripening" effects on the uterine cervix and the promotion of uterine contractile activity (Forman 1982). Intravenous oxytocin has also been used to achieve preinduction cervical ripening, but was found to lack the efficacy when compared to PGE_2 given by various routes (Wilson, 1978). Optimal effect appears to be achieved when prostaglandins were given directly into the endo-cervical canal as compared to intravaginal delivery (Ekman et al 1983).

The present study has demonstrated that a single intracervical application of PGE_2 provided favourable cervical changes as reflected by increased Bishop's scores and shortened induction to delivery intervals and fulfilled the need for minimising systemic side effects. Clearly the use of any PGE_2 preparation is not entirely without risk to mother and the foetus, and may occasionally result in uterine hypertonus. The conditions that most frequently necessitate induction, that is, intra uterine growth retardation, etc, may be associated with placental insufficiency. Hence the "Ripening" period must include careful fetal monitoring throughout the entire latent period but especially during the first 1-2 hours. However it appears on the basis of the present study that PGE_2 gel can be safely used in any setting in which caesarean section can be expeditiously performed if indicated. There was no case of `Failed induction' in the PGE_2 group and hence, the use of PGE_2 gel

can reduce the frequency of caesarean section as also shown by calder et al 1977.

In summary, a single low dose intracervical of prostaglandin E2 gel proved to be a safe and reliable aid in dealing with indicated but potentially difficult inductions. It is easy to use and associated with minimal side effects for mother or foetus.

REFERENCES

1. *Calder A. A., Embrey M. P., Tait T. : Brit. J. Obstet. Gynec. : 84, 264, 1977.*
2. *Ekman G., Forman A., Marsal K. E., Ulmsten U. : Am. J. Obstet. Gynec. : 147, 657, 1983.*
3. *Forman A., Ulmsten U., Banyai J. : Am. J. Obstet. Gynec. : 143, 756, 1982.*
4. *Oury J., Breart G., Bot R & Sureon C. : Revue Fronc. Gynec. : 76, 607, 1981*
5. *Prins R. P., Bolton R. N., Mark C. : Obstet. Gynec. : 61, 459, 1983.*
6. *Trofatter K. F., Bowers D., Gall S. A., Killam P. : Am. J. Obstet. Gynec. : 153, 268, 1985.*
7. *Ulmsten U., Wingerup L., Belfrage P. : Obstet. Gynec. : 59, 336, 1982.*
8. *Verma T. R. & Norman J. : Acta Obstet. Gynec. Scand : 63, 17, 1984.*
9. *Wilson P. D. : Brit. J. Obstet. Gynec. : 85, 941, 1978.*
10. *Yonekura M. D., Songster G., Smith - Wallace T. : Am. J. Perinatol : 2, 305, 1985*