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Clinical trial comparing artificial rupture of membranes plus oral PGE_2 tablets versus artificial rupture of membranes plus intravenous oxytocin for induction of labour in primigravid patients at term

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SUMMARY

We report the results of a pilot study conducted to compare the efficacy of oral prostaglandin E_2 versus intravenous oxytocin in inducing labour after lower amniotomy in 20 primigravid patients at term.

The results suggest no significant differences in the performance of each group for the induction to delivery interval, the mode of delivery, the Apgar score at five minutes or for third stage abnormalities. However, the use of oral PGE_2 allows the patient unrestricted mobility and avoids the discomfort of IV infusions.

INTRODUCTION

The secret of successful induction of labour lies in replicating as accurately as possible the physiological processes of spontaneous labour. In the presence of a favourable cervix, a small dose of prostaglandin E_2 (PGE_2) is often enough to induce a labour very similar to spontaneous labour. This method of induction is also associated with a decrease in postpartum haemorrhage and neonatal jaundice.[1]

The timing of amniotomy is crucial. If performed too early, before the cervix is ripe, it may lead to complications for both mother and fetus. If left too late, we may lose the advantage of its uterine sensitising influence and its augmentatory effect.

Women are requesting less interference with labour and, in particular, as little restriction of mobility as possible during its early stages. A combination of oral PGE_2 and a judiciously timed amniotomy for induction may allow such mobility and may offer a non-invasive alternative to intravenous oxytocin.

PATIENTS AND METHODS

Ethical committee approval of the protocol was obtained and informed written consent obtained from all patients. Twenty patients were recruited. They were all nulliparous at term, with an indication for induction of labour and in the age group 18 to 35 years. Patients with major systemic illness, such as severe bronchial asthma and cardiac disease, and those with existing contraindications to the use of PGE_2 and oxytocin were excluded from the study.

Patients were eligible for the study if, on vaginal examination, the Bishop score was greater than 4.[2]

Each of the twenty patients had low amniotomy (fore water rupture) performed under aseptic conditions using a disposable amnihook. None of the twenty patients were experiencing uterine contractions at the time of artificial rupture of membranes (ARM). They were then randomly

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assigned to two treatment groups. Treatment was commenced within 30 minutes of ARM.

Group 1

Intravenous oxytocin (Syntocinon) was administered according to the standard labour ward regime:

Five units of Syntocinon are added to 500 ml Hartmann's solution and an IVAC pump is used to control the rate of infusion which is commenced at 5 drops per minutes. The dose is increased by 5 drops per minute every 15 minutes until regular uterine contractions are established and are occurring once every three minutes and lasting for at least 40 seconds.

Group 2

PGE_2 (Prostin oral tablets, Upjohn) was administered as an initial dose of 0.5 mg tablet, followed one hour later by 1 mg tablet, and one hour later of 1.5 mg tablet, if the patient is not in established labour. If after three doses the response was poor the options were either to give another 1.5 mg oral dose or to commence intravenous Syntocinon infusion according to the regime prescribed above.

ASSESSMENT

The Bishop score was assessed on entry to the study at the time of low amniotomy (Table I). Cervical dilatation was measured at least every two hours. The frequency, strength and duration of uterine contractions were recorded by the attending midwife, and the time required from commencement of treatment till labour was established (as defined by regular uterine contractions occurring once every three minutes and lasting for at least 40 seconds).

TABLE I

Pre-treatment characteristics (standard deviations in brackets)

	GROUP 1 Amniotomy and IV oxytocin	*GROUP 2 Amniotomy and oral PGE2*
Gestation (weeks)	40.1	40.0
Mean	(2.18)	(2.16)
Bishop score	7.0	6.1
Mean	(1.7)	(1.9)

The duration of the first, second and third stages of labour were recorded, together with the total amniotomy-delivery interval and method of delivery. Analgesic requirements, adverse effects such as vomiting, abnormal cardiotocogram, uterine hypertonus, and presence or development of meconium-stained liquor, were all reported. Apgar scores at one and five minutes and the condition of the baby on transfer from the labour ward were assessed. All maternal and fetal adverse events were carefully documented. The attending doctor and midwife were asked for their subjective assessment and the mother was questioned as to the acceptability of the treatment she had received.

The interval between amniotomy and delivery (Table II) was greater in the oral PGE_2 group, 9.8 hrs, compared with 7.5 hrs for women receiving oxytocin, although these differences were not statistically significant.

TABLE II

Outcome of induction of labour (Standard deviations in brackets)

	GROUP 1 *IV oxytoicin*	GROUP 2 *Oral PGE_2*
– Duration of first stage (hours) (Amniotomy to full cervical dilatation)		
Mean	5.73 (3.40)	7.98 (3.87)
– Duration of second stage (hours)		
Mean	1.63 (1.34)	2.62 (12.8)
– Amniotomy-delivery interval (hours)		
Mean	7.46 (3.95)	9.84 (2.75)
– Mode of delivery		
Normal delivery	7	6
Vacuum extraction	1	0
Forceps	2	2
Caesarean section		1

* 1 patient from the PGE_2 group was changed to IV oxytocin and had a normal delivery.

It was noted that patients went into established labour within one hour of starting IV oxytocin infusion, but not until the third dose of oral PGE_2 was given, ie three hours after ARM. The incidence of spontaneous and instrumental deliveries was similar in the two groups. The two Barnes-Neville forceps deliveries in the oral PGE_2 group were performed because of persistent late decelerations (with 60-90 seconds lag time) on the cardiotocogram. In the IV oxytocin group, two Barnes-Neville forceps deliveries were also performed, the first because of fetal bradycardia and the second because of persistent late decelerations. One vacuum extraction delivery was also performed in this group because of persistent left occipito-transverse position of the head. The patient who required caesarean section (in the oral PGE_2 group) progressed to full cervical dilatation but the fetal head was grossly deflexed in the occipito-posterior position at spines minus one. There were no caesarean sections in the IV oxytocin group.

Of those taking oral PGE_2, one patient developed severe nausea and vomiting after the second dose and had to be changed to IV oxytocin. (In this particular patient, prior to starting IV oxytocin infusion, vaginal examination showed that the cervix was 5-6 cm dilated and fully effaced, and the patient had spontaneous vaginal delivery 3 hours 27 minutes after starting oxytocin infusion.)

The analgesic requirements of those receiving oral PGE_2 were similar to those who had IV oxytocin. Two patients in the IV oxytocin group required epidural analgesia immediately after the oxytocin infusion was commenced. The remaining 18 patients all started with intramuscular pethidine but then requested epidural analgesia. It can be seen from Table III that the mean neonatal birthweight and Apgar scores at one and five minutes were almost the same for each treatment group.

TABLE III

Neonatal outcome

	GROUP 1 IV oxytocin	*GROUP 2 Oral PGE_2*
Number of neonates	10	10
Birthweight (grams) (mean)	3256	3299
Apgar score at 1 minute (mean)	7.9	7.7
Apgar score at 5 minutes (mean)	9.3	9.2

The midwives evaluated both treatments as equally effective in inducing labour.

Of the patients receiving oral PGE_2 tablets, 90% expressed satisfaction with this method of induction, compared with 60% of the women in the oxytocin group. The main reasons for dissatisfaction were the discomfort of the IV line and the restricted mobility in the first stage of labour.

DISCUSSION

The use of oral PGE_2 for the induction of labour has previously been reported and other workers have drawn attention to the ease of administration and increased patient acceptability of this route compared with the use of intravenous infusion. However, previous use was mostly in parous patients with spontaneous rupture of membranes.[3]

Calder et al[1] also reported that oral PGE_2 has been shown to be as effective and safe as oxytocin. Side effects mainly in the form of nausea and vomiting are rarely encountered unless the dose exceeds 1 mg/hour, and they also claimed that the method is more successful in multiparous women, with few side effects seen in this group as the majority respond to low doses.

The problem of nausea, vomiting and diarrhoea appears to be dose-related[4] and can be overcome by applying a low dose regime such as the one used in this study. Hauth et al[5] reported that only one woman vomited in a group of 50 receiving between 0.5 and 1 mg hourly. In this study, only one woman developed severe nausea and vomiting in the oral PGE_2 group and this occurred only with the higher dose of 1 mg tablet.

The mean amniotomy-delivery interval was shorter in the oxytocin group but this did not reach statistical significance (probably because women in the oxytocin group went into established labour quicker than those in the oral PGE_2 group). However, the majority of women in the oral PGE_2 group were in established labour within three hours of initiating treatment and progressed satisfactorily thereafter.

A common criticism of oral administration of oxytocic agents is the prolonged duration of action which can produce problems in patients who develop uterine hypertonus following the

ingestion of the oxytocic agent. However, there were no reported cases of uterine hypertonus in this trial and, in addition, uterine hypertonus can be reversed by urgent administration of a tocolytic, either by infusion or inhalation, to reverse the hypertonia; after an hour, normal labour can usually be allowed to continue.[6]

The women considered oral PGE_2 tablets to be highly acceptable. The most frequently expressed benefits were the ability to be mobile and not being attached to an intravenous infusion.

The midwives did not make any distinctions in the helpfulness of either treatment; this was probably due to initial lack of familiarity with the oral PGE_2 regimen. However, they soon adapted to the new procedure and commented on the simplicity of tablet administration and the fact that PGE_2 patients enjoyed greater mobility during labour.

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