A COMPARISON OF FIVE METHODS OF RIPENING THE UNFAVOURABLE CERVIX PRIOR TO INDUCTION OF LABOUR

by

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Planned induction of labour has become an accepted procedure in modern obstetric practice. One of the factors that influences successful induction of labour is the state of the uterine cervix (Embrey and Anselmo, 1962; Turnbull and Anderson, 1976). If the cervix is closed, uneffaced and firm (unripe), surgical amniotomy is technically difficult and titration with intravenous oxytocin results in prolonged labour with risks of maternal and fetal complications. In patients with unfavourable induction features, there is up to a 42 per cent incidence of Caesarean section for failed induction which has resulted in a need for methods by which the cervix may be ripened.

The use of Foley's catheter in ripening the unfavourable cervix was reported with some success (Embrey and Mollison, 1967; Ezimokhai and Nwabineli, 1980). Prostaglandin (PGE2) oral tablets were inserted vaginally (Gordon-Wright and Elder, 1979; Wilson, 1978) to produce improvement in the Bishop score. Extra-amniotic PGE2 was used to ripen the cervix (Calder and Embrey, 1973, 1977; Shepherd *et al*, 1976; Wilson, 1978) prior to induction and was found to be useful. Intra-vaginal use of PGE2 was found to be effective and simple to administer (Mackenzie and Embrey, 1977, 1978, 1979). Although almost all the published results indicate that prostaglandin E2 is efficient for the purpose of ripening the cervix, it seemed prudent to examine the comparative value of the different methods available in this respect.

This study compared the effect of Foley's catheter and intravaginal PGE2 oral tablets, gel, and pessary on the cervix and the outcome of subsequent labour.

Material and Methods

This study was planned and completed during the course of two years. Five groups of 50 patients consisting of 25 primigravidae and 25 multigravidae were studied.

Patients in Group I had a Foley's catheter (18FG) inserted into the extra-amniotic space and the bulb inflated with 40-50 ml of sterile water.

Patients in Group II received 3 mg of oral PGE2 tablets which were deposited into the posterior fornix of the vagina.

Patients in Group III received 5 mg of PGE2 gel prepared in our pharmacy using 10 ml of K.Y. jelly (which contains 95% hydroxyethyl cellulose and 5% water). PGE2 gel was deposited in the

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posterior vaginal fornix with a syringe. The gel was used usually within 24 hours after preparation, and was stored at 4°C.

Patients in Group IV received 5 mg of PGE2 pessary prepared in our pharmacy using Witepsol S55 base (Dynamit Nobel AG), which was inserted into the posterior fornix of the vagina.

Patients in Group V received 3 mg of PGE2 pessary, which was placed in the posterior vaginal fornix. PGE2 pessary was used within 24 hours after it was prepared and stored at 4°C.

The groups were studied concurrently. The patients were explained the procedure after being recruited either from the antenatal ward or clinic and the decision for induction was made for definite medical and obstetrical indications. The patients from the antenatal clinics were admitted the evening before the planned induction of labour.

Under aseptic condition the cervix was assessed on the modified Bishop's scale (Wilson, 1978). Patients with a Bishop score of less than 4 were chosen for ripening the cervix using one of the methods. At 9 p.m. in the labour ward the cervical os was exposed with a bivalve speculum and the patients in Group I had a Foley's catheter inserted, while Groups 2, 3, 4 and 5 had PGE2 tablets or gel or pessary inserted into the posterior vaginal fornix. The speculum was carefully removed, the time of the treatment was noted, and the fetal heart rate and uterine contractions were monitored with Sonicaid Mark III or Hewlett-Packard Cardiotocograph for at least one hour. If the recordings were satisfactory, and the patient was comfortable and not in labour, she was transferred to the antenatal ward.

Foley's catheter or PGE2 was inserted at 9 p.m. on the day before the planned induction. If labour had not begun by the next morning, the patient was returned to the labour ward, the cervix was reassessed under aseptic conditions and a Bishop score was estimated. The Foley's catheter was removed, if it had not dropped out during the night, then the forewater amniotomy was done and followed by the titrated intravenous administration of 10 units of oxytocin in 1000 ml of 5 per cent dextrose via an Ivac infusion pump. The fetal heart rate and uterine contractions were monitored with the cardiotocograph equipment using scalp clip and intrauterine catheter. The labour was induced exactly the same way for patients in Groups I, II, III, IV and V on the following morning. Further management of labour was by the obstetric staff on duty.

Results

The indications for induction of labour were comparable for the 5 groups (Table I).

Table II shows the details of the results of induction of labour in the five groups.

The mean age and the mean gestation at induction were comparable for the primigravidae and multigravidae in all the 5 groups of patients. The mean pre-treatment Bishop score was also comparable for the 5 groups. The difference was not significant ($P > 0.05$). However, when the post-treatment Bishop score was compared for the 5 groups, both the primigravidae and multigravidae had significant improvement in the groups receiving PGE2 gel or pessary ($P < 0.01$). The groups IV and V using PGE2 pessary appeared to have a better Bishop score as compared with Group III using PGE2 gel. Our study showed that 3 mg PGE2 pessary produced significant change in the cervical score as compared with other

TABLE I
Main Indications for Induction for the 5 Groups

Main Indications	Group I (n = 50) (Foley's Catheter)		Group II (n = 50) (Intra-vaginal PGE_2 tablet 3 mgm)		Group III (n = 50) (Intra-vaginal PGE_2 gel 5 mgm)		Group IV (n = 50) (Intra-vaginal PGE_2 pessary 5 mgm)		Group V (n = 50) (Intra-vaginal PGE_2 pessary 3 mgm)	
	No.	%	No.	%	No.	%	No.	%	No.	%
Hypertension	12	(24%)	14	(28%)	13	(26%)	12	(24%)	11	(22%)
Pre-eclampsia	9	(18%)	10	(20%)	9	(18%)	9	(18%)	10	(20%)
Post-term	10	(20%)	9	(18%)	9	(18%)	10	(20%)	11	(22%)
Fetal growth retardation	8	(16%)	7	(14%)	7	(14%)	8	(16%)	9	(18%)
Static weight	8	(16%)	6	(12%)	7	(14%)	7	(14%)	6	(12%)
Breech	—	—	1	(2%)	2	(4%)	2	(4%)	2	(4%)
Others	3	(6%)	3	(6%)	3	(6%)	2	(4%)	1	(2%)

methods. The difference was not significant when compared with the effects produced by 5 mg of PGE2 pessary.

The number of patients with low post-treatment cervical score was significantly higher for Group I who used Foley's catheter and Group II who received PGE2 tablets as compared with the Groups III, IV and V who received PGE2 gel or pessary. Groups IV and V who received PGE2 pessary appeared to have a low incidence of low cervical score ($P < 0.01$). Groups IV and V who received PGE2 pessary 5 mg and 3 mg respectively had an incidence of 68 per cent and 70 per cent of spontaneous onset of labour which was significantly higher as compared with those in Groups I, II and III. PGE2 pessary appeared to be more successful in inducing spontaneous labour ($P < 0.01$).

The induction delivery interval was less in Groups IV and V, which received PGE2 pessary ($P < 0.01$) as compared with that in Groups I, II and III.

Our study showed that the PGE2 pessary 3 mg was as effective as 5 mg and the pessary appeared to be more effective in improving the cervical score and the subsequent outcome of labour.

Table III shows the details of delivery.

Groups IV and V who received PGE2 pessary had the lowest incidence of Caesarean section (8-10%) and the highest incidence of normal delivery (78%). The difference was highly significant when the incidence of normal delivery and Caesarean section in Groups I and II was compared. The incidence of Caesarean section for fetal distress was significantly low in the Groups IV and V and there were no patients in these two groups who required a Caesarean section for failed induction ($P < 0.01$). Signi-

TABLE II

Results Following Ripening of the Cervix and the Outcome of Induction of Labour in the 5 Groups

	Group I (Foley's Catheter)			Group II (PGE_2 Tablets 3 mgm)		
	Primi-gravidae (n=25)	Multi-gravidae (n=25)	Total (n=50)	Primi-gravidae (n=25)	Multi-gravidae (n=25)	Total (n=50)
Age of Patients (years) Mean ± SD	24.4 ± 3.2	28.0 ± 3.4	26.2 ± 3.4	24.8 ± 3.1	28.2 ±3.3	26.6 ± 3.2
Gestational age at induction (weeks) Mean ± SD	40.7 ± 1.4	39.8 ± 1.3	40.3 ± 1.35	40.6 ± 1.6	39.8 ± 1.2	40.2 ± 1.4
Pre-treatment Bishop Score Mean ± SD	2.5 ± 1.1	2.8 ± 1.1	2.65 ± 1.2	2.6 ± 1.1	2.9 ± 1.05	2.76 ± 1.08
Post-treatment Bishop Score Mean ± SD	5.8 ± 2.1	6.8 ±2.4	6.3 ± 2.3	5.0 ± 2.3	6.9 ± 2.5	6.4 ± 2.4
Mean increase in Bishop Score	3.3	4.0	3.65	3.3	4.0	3.65
Number of patients with post-treatment low Bishop Score (<5) (%)	8 (32%)	5 (20%)	13 (26%)	7 (28%	5 (20%)	12 (24%)
Number of patients in spontaneous labour (%)	2 (8%)	4 (16%)	6 (12%)	4 (16%)	6 (24%)	10 (20%)
Induction delivery interval (hours) (excluding C/S) Mean ± SD	13.8 ± 2.9	9.6 ± 3.1	11.7 ± 3	12.6 ± 3.0	9.4 ± 3.4	11.0 ± 3.2

ficantly less patients required epidural analgesia in Groups IV and V ($P < 0.01$). The incidence of post-partum haemorrhage was low in Groups IV and V as compared with that of Groups I and II.

Our study showed that 3 mg PGE2 pessary was associated with better outcome with less need for epidural analgesia. This might be due to the shorter duration of induction delivery interval.

Table IV shows the fetal status in the five groups.

The average birthweight of infants was comparable for the 5 groups.

The mean Apgar score was better in the Groups IV and V, though the dif-

TABLE II (Contd.)

Group III (PGE gel 5 mgm)			Group IV (PGE_2 Pessary 5 mgm)			Group V (PGE_2 pessary 3 mgm)		
Primi-gravidae (n=25)	Multi-gravidae (n=25)	Total (n=50)	Primi-gravidae (n=25)	Multi-gravidae (n=25)	Total (n=50)	Primi-gravidae (n=25)	Multi-gravidae (n=25)	Total (n=50)
24.2 ± 3.1	29.2 ± 3.5	26.7 ± 3.3	24.8 ± 3.1	29.2 ± 3.4	2.7 ± 3.3	24.7 ± 3.3	29.6 ± 3.6	27.2 ± 3.45
40.4 ± 1.4	39.6 ± 1.2	40 ± 1.3	40.6 ± 1.4	39.2 ± 1.6	39.9 ± 1.5	40.3 ± 1.4	39.9 ± 1.3	40.1 ± 1.35
2.6 ± 1.02	2.9 ± 1.1	2.75 ± 1.06	2.7 ± 1.7	2.9 ± 1.1	2.8 ± 1.1	2.5 ± 1.03	2.9 ± 1.1	2.7 ± 1.07
7.2 ± 2.4	8.9 ± 2.3	8.05 ± 2.36	8.9 ± 2.5	9.9 ± 2.8	9.4 ± 2.75	8.9 ± 2.6	10.3 ± 2.9	9.6 ± 2.75
4.6	6.0	5.3	6.2	7.0	6.6	6.4	7.4	6.9
4 16%)	2 (8%)	6 (12%)	2(8%)	1(48%)	3 (6%)	1 (4%)	1 (4%)	2 (4%)
12(48%)	15(60%)	27 54%)	15(60%)	19(76%)	34 (68%)	16(64%)	19(76%)	35 (70%)
10.4 ± 2.8	7.0 ± 2.9	8.7 ± 2.85	8.9 ± 2.4	6.1 ± 2.6	7.5 ± 2.5	8.2 ± 2.6	6.1 ± 2.8	7.15 ± 2.7

ference was not highly significant. However, the number of infants with low Apgar score at one and five minutes 0-5) was significantly less in the Groups IV and V ($P < 0.01$).

The incidence of fetal distress was less in Groups IV and V and the difference between Groups IV and V, and I and II was highly significant (< 0.01).

Discussion

The principle of priming or ripening the cervix with prostaglandins before planned induction of labour was first proposed and investigated by Calder *et al* (1977). Their method entailed the extra-amniotic administration of a small dose of PGE2, 250-400 μg in a viscous gel, using

TABLE III
Details or Delivery in the 5 Groups

Details of Delivery	Group I (Foley's Catheter)			Group II (PGE_2 Tablets 3 mgm)		
	Primi-gravidae (n=25)	Multi-gravidae (n=25)	Total (n=50)	Primi-gravidae (n=25)	Multi-gravidae (n=25)	Total (n=50)
Normal Delivery (%)	14(56%)	16(64%)	30(60%)	15(60%)	17(68%)	32(64%)
Forceps Delivery (%)	6(24%)	5(20%)	11(22%)	6(24%)	4(16%)	10(20%)
Caesarean Section (%) (C/S)	5(20%)	4(16%)	9(18%)	4(16%)	4(16%)	8(16%)
Indications for C/S						
Failure to progress (failed induction)	3(12%)	2(8%)	5(10%)	2(8%)	2(8%)	4(8%)
Fetal Distress	2(8%)	2(8%)	4(8%)	2(8%)	2(8%)	4(8%)
Breech	—	—	—	—	—	—
Cephalopelvic disproportion	—	—	—	—	—	—
Increasing Hypertension in Labour	—	—	—	—	—	—
Epidural Analgesia	15(60%)	13(52%)	28(56%)	14(56%)	13(52%)	27(54%)
Post-partum Haemorrhage	2(8%)	2(8%)	4(8%)	1(4%)	2(8%)	3(6%)

a self-retained Foley's catheter inserted through the cervical canal. It resulted in a considerable reduction in the duration of labour, less need to resort to Caesarean section, and improvement in the condition of the neonate.

We studied 5 groups of patients. The Foley's catheter was initially tried for those who had an unfavourable cervical score. If this method was efficient, it would have been simple, easy, and less expensive to used. We did not find this method very useful. Thirteen of 50 (26%) patients still had a cervical score less than 4 on the morning after the insertion of Foley's catheter and only 6 out of 50 (12%) had a spontaneous onset of labour. The overall incidence of Caesarean section was 18 per cent, and 10 per cent of Caesarean sections were done for failed induction, while 8 per cent were done for fetal distress. Fourteen per cent of the infants had a low Apgar score. Embrey and Mollison (1967) were the first to investigate the use of Foley's catheter in ripening the cervix and stated that the cervical score improved sufficiently so that amniotomy was possible in most cases. However, Ezimokhai and Nwabineli (1980) studied 21 primigravidae and stated

TABLE III (Contd.)

Group III (PGE_2 gel 5 mgm)			Group IV (PGE_2 Pessary 5 mgm)			Group V (PGE_2 Pessary 3 mgm)		
Primi-gravidae (n=25)	Multi-gravidae (n=25)	Total (n=50)	Primi-gravidae (n=25)	Multi-gravidae (n=25)	Total (n=50)	Primi-gravidae (n=25)	Multi-gravidae (n=25)	Total (n=50)
17(68%)	18(72%)	35(70%)	19(76%)	20(80%)	39(78%)	19(76%)	20(80%)	39(78%)
4(16%)	4(16%)	8(16%)	4(16%)	3(12%)	7(14%)	3(12%)	3(12%)	6(12%)
4(16%)	3(12%)	7(14%)	3(8%)	2(8%)	4(8%)	2(8%)	2(8%)	5(10%)
1(4%)	—	1(2%)	—	—	—	—	—	—
1(4%)	1(4%)	2(4%)	—	1(4%)	1(2%)	—	1(4%)	1(2%)
1(4%)	—	1(2%)	1(4%)	—	1(2%)	—	1(4%)	1(2%)
1(4%)	2(8%)	3(6%)	1(4%)	—	—	2(8%)	—	2(4%)
—	—	—	—	1(4%)	1(2%)	1(4%)	—	1(2%)
13(52%)	10(40%)	23(46%)	12(48%)	9(36%)	21(42%)	11(44%)	8(32%)	19(38%)
—	1(4%)	1(2%)	—	2(8%)	2(4%)	—	1(4%)	1(2%)

that they found the Foley's catheter was as useful as PGE2 gel. They stated that the improvement in cervical score, the number of patients who started labour spontaneously, the induction-delivery interval, the incidence of Caesarean section for fetal distress and failed induction were not different for the 21 patients who had Foley's catheter and 14 patients who received PGE2 gel. Our results did not confirm their findings and our patients had a less favourable outcome.

Oral PGE2 tablets were used vaginally by Wilson (1968) and Gordon-Wright and Elder (1979). Wilson showed from his study that vaginal PGE2 tablet was second-best among the 4 groups who received extra-amniotic PGE2 gel, oxytocin infusion, intra-vaginal PGE2 tablets, and oral PGE2 tablets. It was second-best in improving the cervical score, in establishing spontaneous labour and in achieving normal vaginal delivery. The incidenee of Caesarean section was similar for vaginal PGE2 tablets and extra-amniotic PGE2 gel, but 2 of 15 (13.3%) patients using PGE2 tablet required Caesarean section for failed induction as compared with no failure in the group with extra-amniotic PGE2 gel. Wilson (1978) also stated that

TABLE IV
Fetal Status in the 5 groups

	Group I (Foley's Catheter) (n=50)	Group II (PGE_2 tablet 3 mgm) (n = 50)	Group III (PGE_2 gel 5 mgm) (n=50)	Group IV (PGE_2 pessary 5 mgm) (n = 50)	Group V (PGE_2 pessary 3 mgm) (n = 50)
Birthweight of babies (Kg) Mean ± SD	3.263 ± 0.485	3.481 ± 0.415	3.409 ± 0.512	3.389 ± 0.482	3.396 ± 0.476
Fetal Distress in Labour	5 (10%)	5 (10%)	4 (8%)	3 (6%)	2 (4%)
Mean Apgar Ssore at one minute	7.2	7.8	8.92	9.22	9.24
Number of Babies with low Apgar Score (0-5) (%)	7 (14%)	7 (14%)	5 (10%)	3 (6%)	3 (6%)

vaginal PGE2 tablets had the advantage of being simple and were found to be more acceptable to patients but were not as effective as extra-amniotic PGE2. Gordon-Wright and Elder (1979) showed that vaginal PGE2 tablets were useful in ripening the cervix and inducing labour in 56.7 per cent.

Our study of 50 patients who received (3 mg) tablets as single insertion had similar outcome of labour and delivery as those who had Foley's catheter. Only 20 per cent in this group had a spontaneous onset of labour. The mean increase in cervical score (3.65), the incidence of post-treatment low cervical score (24%), induction-delivery interval (10.3 hours), Caesarean section for failed induction (8%) and fetal distress (8%) were comparable with those in the group who had Foley's catheter. However, these results were better than those reported for those who had an amniotomy without cervical ripening. The results in the series studied by Gordon-Wright and Elder (1979) were better, but this may be due to a higher pre-induction cervical score in their patients.

Mackenzie and Embrey (1977, 1978, 1979) showed PGE2 gel was simple to use and its effect on the cervix and the subsequent outcome on labour was significant. Its effect on the fetus was significantly better as compared with those who had amniotomy without priming the unfavourable cervix. They reported that 49-69 per cent of patients started labour spontaneously. The need for intravenous syntocinon and epidural analgesia, the incidence of Caesarean section for fetal distress and failed induction and the number of infants with low Apgar score were significantly low when PGE2 gel was used prior to induction.

Our study confirmed the PGE2 gel was simple to use and was more effective than PGE2 tablet and Foley's catheter. However, PGE2 pessary containing 5 and 3 mg was found to be most effective and was associated with most favourable out-

come out of the 5 groups studied. Two multigravidae in Group III and 2 multigravidae in Group IV receiving 5 mg of PGE2 showed hypertonic uterine activity which settled down with ritodrine infusion and eventually had vaginal delivery and all infants were in good condition at birth. Since 3 mg of PGE2 pessary was as effective as 5 mg and was safer for multiparous women, we now routinely use 3 mg of PGE2 pessary. There were no cases of hypertonic activity when 3 mg of PGE2 pessary was used. Our study shows that the vaginal administration of PGE2 pessary (3 mg) prior to planned induction of labour is a simple, non-invasive, safe and effective technique which ripens the cervix and thereby improves the prognosis in labour. A further study was planned to evaluate the use of PGE2 pessary as a method of induction labour.

Summary

A comparison was made between five methods of ripening the unfavourable cervix: Foley's catheter, intravaginal prostaglandin E2 tablet (PGE2 3 mg), PGE2 gel (5 mg), PGE2 pessary (5 mg), PGE2 pessary (3 mg) in a trial involving 250 patients, 125 primigravidas and 125 multigravidae. There was an improvement in cervical status in all groups. This was significantly greater in those patients who received intravaginal PGE2 pessary ($P < 0.01$). They had a significant decrease in the mean induction-delivery interval and in the incidence of Caesarean section for failed induction and fetal distress ($P < 0.01$).

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