

# **A DOUBLE BLIND CONTROLLED TRIAL TO STUDY THE EFFECTS OF VAGINAL PROSTAGLANDIN PESSARIES ON INDUCTION OF LABOUR AND IMPROVEMENT IN THE FAVOURABILITY OF THE CERVIX**

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## **INTRODUCTION**

Induction of labour when the cervix is unfavourable is said to reduce the chances of a vaginal delivery (<sup>2,9</sup>). Many methods have been used to "ripen" the cervix to promote vaginal delivery (<sup>2,3,4,6</sup>).

Vaginal prostaglandin pastes and pessaries have been used to improve the favourability of the cervix for induction for a number of years (<sup>6,7,9</sup>). There has, however, never been a double blind trial to assess the effect of vaginal prostaglandin pessaries on either, improving the Bishop score (<sup>1</sup>) or the effect of prostaglandins in inducing labour.

A double blind trial was therefore performed at Sunderland District General Hospital to assess the effect of prostaglandin pessaries on both the Bishop score and induction of labour.

## **METHOD**

All patients for whom induction of labour was considered necessary were included in the trial. They were admitted the night before induction and informed consent was obtained. Following a cervical assessment at which a Bishop score was recorded, a vaginal pessary (containing either 3 mgs prostin E<sub>2</sub> or placebo) was inserted into the posterior vaginal fornix at approximately 22.00 hours.

The patients were requested to remain in bed for 30 minutes after this procedure. Established labour was diagnosed by the onset of regular, painful contractions, dilatation of the cervix and/or spontaneous rupture of membranes. If labour was not established by 09.00 hours the following morning, forewater amniotomy and oxytocin infusion were commenced and the Bishop score was reassessed. Those starting labour spontaneously after insertion of the pessary were transferred to the labour suite and labour was then managed actively with rupture of membranes and oxytocin infusion.

The duration of labour, type of delivery, one and five minute Apgar scores were recorded.

## **DISPENSING PROCEDURE**

Prostin E<sub>2</sub> 3 mgs (Upjohn Ltd.) was prepared in a Witsepol S55 base (Dynamit Nobel) and stored in a refrigerator

## **SUMMARY**

In a double blind trial of prostaglandin pessaries to induce labour, prostaglandins were successful in 47.5% of primiparous and 70.6% of multiparous patients. Of the 66% who did not go into labour this was successfully induced by artificial rupture of the membranes and oxytocin infusion in all but two cases irrespective of whether or not they received the active compound. This trial suggests that prostaglandin pessaries are a useful and very acceptable way of inducing labour and that although they make the cervix more "favourable" they do not significantly alter the outcome of labour. In the light of their high cost it is time that this method of induction and its timing was re-evaluated.

## **ACKNOWLEDGEMENTS**

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Table 1. — *Number of patients successfully induced after insertion of pessaries.*

	Primiparous Bishop's score			Multiparous Bishop's score			Total
	≤6	>6		≤6	>6		
Prostin	25/57	23/44	48/101	34/49	26/36	60/85	108/186
Placebo	2/42	4/41	6/83	2/55	7/41	9/96	15/179
	(χ <sup>2</sup> y = 33.76; P < 0.001) Primiparous			(χ <sup>2</sup> y = 60.04; P < 0.001) Multiparous			

(2 to 8 °C) by the hospital pharmacy. The placebo pessary was prepared in the same way except that 4 mls of absolute alcohol was substituted for the prostin solution.

Numbers 1 to 400 were randomly chosen and alternately allocated to placebo or treatment groups on the dispensing record form. The code was broken at the end of the trial.

## RESULTS

A total of 365 patients entered the trial of whom 184 (50.4%) were primiparous and 181 (49.6%) multiparous. The most common indications for induction were post-maturity (72%) and pre-eclampsia (17.5%).

The outcome in terms of successful induction of labour is shown in table 1. Overall, prostaglandins were effective in inducing labour in 58% of all patients receiving the active compound, whereas only 8.3% of the patients receiving placebo went into labour. Using χ-square with Yates' correction (χ<sup>2</sup>y), this was statistically significant both for primiparous patients (χ<sup>2</sup>y = 33.76; P < 0.001) and for multiparous patients (χ<sup>2</sup>y = 69.04; P < 0.001) irrespective of a poor Bishop score.

Of the 57 primiparous patients receiving a prostaglandin pessary with a Bishop score ≤6 43.8% went into labour, compared to only 4.8% of the 42 patients receiving placebo (χ<sup>2</sup>y = 18.6; P < 0.001) (table 1).

Of the 140 patients with a poor Bishop score (≤6) that did not go into labour the Bishop score improved in both primiparous patients (χ<sup>2</sup>y = 2.21; P = 0.136) and multiparous patients (χ<sup>2</sup> = 6.18; P = 0.013) (table 2). The Bishop score however, was a poor prognostic indication of successful induction as there was no significant increase in the length of labour in any group (table 3) and in only 21 cases was labour greater than 12 hours. Only

Table 2. — *Number of patients whose Bishop's score improved from unfavourable (≤6) to favourable (<6) after pessary insertion.*

	Primiparous	Multiparous	Total
Prostin	16/32	13/15	29/47
Placebo	12/40	24/53	36/93
			65/140

χ<sup>2</sup>y = 2.21; P = 0.136 Primigravidae  
χ<sup>2</sup>y = 6.18; P = 0.013 Multigravidae

Table 3. — *Duration of labour and number of caesarean section for failed induction.*

	Successful pessary induction		Induction by A.R.M. and Oxytocin		Caesarean section for failed induction
	<8 hours	≥8 hours	<8 hours	≥8 hours	
Primiparous:					
Prostin	31	17	43	10	0
Placebo	4	2	55	22	1
Multiparous:					
Prostin	56	4	23	2	0
Placebo	9	0	74	13	1

2 patients required caesarean section for failed induction, both in the placebo group, and there were no problems in any patient with uterine hypertonus or associated fetal distress.

There was no significant difference in the gestational age, birth weight and one and five minute Apgar scores in the two groups of patients.

## DISCUSSION

These results suggest that prostaglandin pessaries are a good way of inducing labour whether the cervix is judged favourable or not but does little to improve inducibility in those patients who do not go into labour. Although the Bishop score was improved there was no significant delay in those patients who were regarded as unfavourable, and this calls into doubt the value of this score as a means of assessing the ease of induction. The effects of prostaglandins are synergistic with that of oxytocin and last up to 6 hours post-insertion, particularly with the new prostaglandin tablet<sup>(5)</sup>.

The current practice of inserting prostaglandin pessaries the night prior to induction should perhaps be reconsidered in the light of these data as the major effect seems to be that of inducing labour and this currently occurs through the night. Thus, it is the apparently "at risk" fetus in whom induction is considered necessary, that is being delivered when senior midwifery and medical care is least

available. It would seem more sensible to insert the pessaries early in the morning and proceed to artificial rupture of membranes (ARM) late morning if labour does not commence.

Prostaglandins remain a socially very acceptable but high cost way of inducing labour, and should they fail, which will occur in 42% of patients, ARM and oxytocin infusion will be required.

However, in these days of financial constraints ARM followed by oxytocin infusion remains a cheap and as effective method of induction of labour, particularly as many patients will subsequently require augmentation.

These findings are at variance with those published but it remains the only double blind controlled study.

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