BUCCAL PITOCIN

A Small Clinical Trial

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The use of oxytocin by the oral route has long been considered to be ineffective on uterine activity. In January 1964 I learnt that a Pitocin product for buccal administration had been under clinical trial for a few years, including two years in Britain. Through a visiting representative of the manufacturers I expressed interest in this product, and I was then invited by their Department of Clinical Investigation to participate in the final stages of the trial, prior to their release of this new preparation on the commercial market.

Material and Method

Sufficient tablets were provided for a clinical trial in 30 cases. For each case full details were required on a special reporting form, set specifically for I.B.M. coding. Information was sought about the patient, her labour and the infant.

Each tablet of Buccal Pitocin contains 200 units of oxytocin. It is rectangular in shape, thin and flat to provide a relatively large surface for absorption. It is placed in the parabuccal cheek-pouch adjacent to the upper molar teeth.

The dosage scheme adopted for this clinical trial was the one recommended by the manufacturers (but not all investigators have adopted this). Treatment is initiated with half a tablet (i.e. 100 units), which is repeated after an interval of 30 minutes. Increments in dosage are made up to a maximum of three whole tablets, in this manner:

0	hr	—	½ tab.
½	hr	—	½ tab.
1	hr	—	1 tab.
1½	hr	—	1 tab.
2	hr	—	2 tab.
2½	hr	—	2 tab.
3	hr	—	3 tab.
3½	hr	—	3 tab.
4	hr	—	3 tab.
4½	hr	—	3 tab.
5	hr	—	3 tab.

Since the tablets take more than 45 minutes to disintegrate and be absorbed, then at the time when the largest dose is being administered there will be in the patient's mouth three fresh tablets and three partially absorbed tablets.

The full course of 22 tablets or 4,400 units takes five hours to administer, so that it is best to commence it at 8 a.m. or thereabout. By 1 p.m. the patient will then be in progressive labour — or else the treatment is abandoned for the day. Quite often labour is well established before the full course has been given, and the tablets are then discontinued.

In the course of this clinical trial, the following notes were circulated to the midwifery staff:

"Strict supervision is necessary throughout administration. If pains become too frequent or too strong, remove tablets and rinse the mouth with water.

The above dosage scheme is never exceeded on one day.

The tablets will only be effective so long as they are not swallowed or even sucked.

During the course of administration of these tablets, it is preferable to avoid feeding and drinking altogether. Conversation is also to be restricted, since any dislodgement of the tablets may easily interfere with their activity.

Please ensure that the usual labour record is complete in every case."

All the patients in this clinical trial were in the Ante-Natal Ward of St. Luke's Hospital. They were delivered over a 4-week period.

Twenty-seven women were included in the trial, some of them receiving more than one course of tablets. Their ages ranged between 19 and 40 years, more than half of them being below 30 years of age. The parity varied considerably, as shown in Table I (where all miscarriages have been disregarded). In the majority of cases the period of gestation was 40 + or – 1 weeks, except in the following cases: one at 36 weeks, and one at 37, one at 42 and two at 43.

TABLE I

Parity	*Number*	*Percentage*
0	7	25.9
1	9	33.4
2	4	14.8
3, 4 or 5	Nil	—
6 or more	7	25.9
Total	27	100

The indication for administering the tablets are listed hereunder:

TABLE II

Indication	*Number*	*Percentage*
Inert labour	14	51.8
Postmaturity	5	18.6
Premature rupture of membranes	4	14.8
Failed surgical induction	2	7.4
Toxaemia	1	3.7
Previous intra-uterine death	1	3.7
Total	27	100

Results

Complete failure in effecting delivery occurred in only 3 cases (11 per cent.). In a further 4 cases the first course of buccal Pitocin failed to promote labour, and successful induction was elicited on the next day by means of artificial rupture of the membranes combined with a second course of buccal Pitocin. In the remaining 20 cases the tablets were fully successful: in 16 cases on the first day, and in 4 cases with the second-day course.

Delivery was spontaneous in 24 cases,

and by forceps in three. There was no maternal mortality, no still-birth and no neo-natal death. There was one case of postpartum haemorrhage. In another case there was retention of a small piece of placenta. There was no uterine hyperactivity, nor any case of rupture of the uterus.

Discussion

The results of this small trial were included in a report circulated by the manufacturers of the tablets to their clinical investigators. The report was in the form of a review of the 1860 patients treated in these European trials.

The over-all success rates were 66% for induction of labour and 89% for stimulation of inert labour. By and large, induction required double the dose compared with stimulation. Treatment beyond the third day was not considered worthwhile; this agrees with the findings of Krzaniak (1965).

Induction in 38 patients who had previous Caesarean section was uneventful in all but one case, where there was rupture of the uterus — to which other factors certainly contributed in this woman.

Uterine hyperactivity is an important complication. It occurred in 35 mothers (almost 2 per cent.), with rupture of the uterus in two cases. This emphasises the absolute necessity for continuous observation of the mother during the administration of these tablets.

There is no doubt that Buccal Pitocin provides an effective and convenient method for the induction and stimulation of labour. Favourable reports on its use have been appearing in the medical literature at regular intervals (Dillon et al., 1960; Elstein and Payling-Wright, 1963; Pinkerton, 1964; Chung, 1966). Nevertheless there are occasions when it can be very dangerous, especially when misused. In the literature reference has already been made to 8 cases of uterine rupture, and some authors have strongly condemned the use of these tablets (Best, 1964; Gate, 1964; Theobald, 1965).

In an attempt to increase the margin of safety, dosage schemes are being evolved employing tablets containing only 100 units of oxytocin. Indeed, Chalmers and Moorhouse (1966) report good results with surprisingly low doses: beginning with only 10 units and rising up to 75 units, with a maximum total intake of merely 535 units (in contrast to the 4400 units employed in the original trials).

It is criminal to employ Buccal Pitocin haphazardly. Its administration demands very careful clinical assessment of the individual case as well as continuous and meticulous supervision. These are basic essentials. To disregard them is to invite serious disaster. The use of Buccal Pitocin entails the same precautions as intravenous oxytocin, but the former is very much more convenient than the latter — and much less of an endurance trial for the patient.

Correctly used, Buccal Pitocin is a veritable boon to modern obstetric practice.

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