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Ethics and Halothane

SIR,—Dr. J. M. K. Spalding is wrong (21 September, p. 739). There is no evidence in your leading article (7 September, p. 589) to suggest that many well-informed and responsible doctors "believe in an association between repeated exposure to halothane and liver damage." What is made clear is that the Committee on Safety of Medicines was ill-informed and behaved precipitately by circulating a warning letter¹ on the dangers of halothane without waiting for the discussion of the scientific merits of the paper² on which the letter was based and that subsequently certain ethical committees behaved equally unwisely by interfering with the anaesthetists' right to decide what anaesthetic agent can or cannot be used in a specific clinical situation.

What is at issue is not whether halothane on rare occasions is associated with liver damage but whether the patient will come to less harm if halothane is not used and some other drug or technique is substituted. The evidence on this point is, to say the least, equivocal and Dr. Spalding's letter does anaesthetists a great disservice. In the present state of our knowledge the choice of an anaesthetic technique must be made by the anaesthetist concerned on the basis of his clinical experience, and the ill-judged letters from the Committee on Safety of Medicines and from Dr. Spalding have done nothing to make his task easier.

I cannot accept Dr. Spalding's assertion that members of ethical committees who followed the advice of your article would "find themselves joined with the anaesthetists in any action for negligence." Such an assertion could have serious repercus-

sions for anaesthetists and other clinicians were it not for the fact that the Medical Research Council has expressed quite the contrary view:

"In the light of a review of existing data and of expert advice, the Council are agreed that these data are insufficient to enable a comparison to be made of the total risks from more than one exposure to halothane with those from the repeated use of other anaesthetics. The Council take the view that the question may best be resolved by undertaking a prospective survey of the incidence of liver disfunction and other effects following repeated exposures to halothane and to other anaesthetics."³

Thus anaesthetists and others who are concerned about the medicolegal implications of repeated exposure to halothane need not be too worried. They can be sure that in this connexion any decision based on their clinical judgement will have not only the backing of the great majority of their colleagues but also the moral support of the Medical Research Council.

From a broader aspect, the current controversy arose as a result of the distribution of the circular letter on the subject by the Committee on Safety of Medicines and Professor J. Parkhouse (28 September, p. 807) is surely right when he asks if it is a proper part of the Committee's function "to enter the arena of clinical judgement in the use of drugs." Many of us would like to see that question answered.—I am, etc.,

J. P. PAYNE

Research Department of Anaesthetics,
Royal College of Surgeons of England,
London W.C.2

¹ Mansell-Jones, D., CSM/AR/S/121, 3 January, 1974.

² Inman, W. H. W., and Mushin, W. W., *British Medical Journal*, 1974, 1, 5.

³ *British Medical Journal*, 1974, 3, 268.

Dangers of Oxytocin-induced Labour to Fetuses

SIR,—Like Mr. W. A. Liston and Mr. A. J. Campbell (7 September, p. 606) and Mr. G. V. P. Chamberlain (14 September, p. 684) we have been concerned with the possible undesirable side effects of drugs used to induce or stimulate labour. In two studies comparing oxytocin and prostaglandin E₂ (PGE₂) for the induction and augmentation of labour we fulfilled the criteria suggested by Mr. Chamberlain.

A group of consecutive patients in whom labour was to be induced or augmented were given one of the drugs (PGE₂) and these patients were then carefully matched according to age, parity, maturity, and Bishop's score or cervical dilatation with a group of patients given oxytocin. The obstetric management, apart from the stimulant drugs, was identical in the two groups. For intravenous therapy a constant-rate infusion pump was used, and all labours were continuously monitored by means of a presenting-part electrode and an intra-uterine pressure catheter. A double-blind trial was not considered ethical.

In the induction series¹ there was no significant difference between the two groups in induction-to-delivery interval, Apgar scores at one and five minutes, or incidence of post-partum haemorrhage. However, resting uterine tone, frequency of uterine contractions, and incidence of incoordinate

uterine activity were significantly greater in the oxytocin group than in the PGE₂ group.

In the augmentation series² the difference between the two drugs was even more apparent. The augmentation-to-delivery interval, the mean basal uterine tone, the mean frequency of contractions, nausea, vomiting, ketosis, pyrexia, and late fetal heart decelerations were all significantly higher in the oxytocin group than in the PGE₂ group.

Returning to Mr. Chamberlain's observation that preselection of high-risk infants may explain the findings of Mr. Liston and Mr. Campbell, our data demonstrate that the oxytocic used is undoubtedly a contributory factor. They also show that this is less significant with PGE₂ than with oxytocin. We therefore support Mr. Liston and Mr. Campbell's suggestion that the use of oxytocin can be hazardous and, while PGE₂ appears to be kinder to the uterus and fetus, the possible dangers of all oxytocics should never be forgotten.—We are, etc.,

JOHN KELLY
A. M. FLYNN

Birmingham Maternity Hospital,
Birmingham

- 1 Kelly, J., Flynn, A. M., and Bertrand, P. V., *Journal of Obstetrics and Gynaecology of the British Commonwealth*, 1973, 80, 923.
- 2 Clegg, D. R., Flynn, A. M., and Kelly, J., *Journal of Obstetrics and Gynaecology of the British Commonwealth*. In press.

SIR,—Mr. W. A. Liston and Mr. A. J. Campbell (7 September, p. 606) correctly remind us that oxytocic stimulation of labour carries risks and that the fetal heart and the intrauterine pressure should be monitored. It is no surprise that stimulated labour results in babies with a lower mean Apgar score than normal labour but erroneous to attribute this to the effects of acceleration of labour. The authors did not report the duration of labour, the timing of oxytocic stimulation, or the mode of delivery. It is therefore pertinent to elaborate the penalties of non-interference of dysfunctional labour.

The object of acceleration of labour is not to speed up labour which is progressing at a normal rate. Such unselective stimulation can be avoided by reference to the labour stencil or nomogram,¹ which when used in conjunction with partograms clearly separates normal from high-risk labour.

We have shown that a normal delivery occurred in 82% of primigravidae whose cervimetric progress kept to the left (Group A) or up to two hours past the nomogram (Group B) (see fig.). For multigravidae the proportion was 95%. Labours progressing past this mark, if unstimulated, had only a 30% normal delivery rate regardless of parity. Unstimulated primigravidae have a 10% caesarean section rate (Group D). The duration of the first and second stages of labour was longer and the mean Apgar score was lower in dysfunctional labour than in either dysfunctional stimulated labour (Group C) or normal labour (Groups A and B). The less satisfactory results of Group D occurred in spite of the fact that these patients were admitted with a greater mean cervical dilatation than those who were stimulated and were adjudged by the ob-

Obstetric outcome in 349 consecutive spontaneous primigravid labours in relation to the nomogram and oxytocin stimulation. Groups A and B not stimulated; group C stimulated; group D non- or late stimulation.

stetrician to be in reasonably normal labour not requiring any help from oxytocics.

Contrary to the conclusions of Mr. Liston and Mr. Campbell these results show the dangers of non-stimulation and the need to use a nomogram representing normal labour in order to identify the 25% of primigravidae and the 10% of multigravidae who will benefit from acceleration of labour.—We are, etc.,

JOHN STUDD

King's College Hospital,
London S.E.5

D. R. CLEGG

Birmingham Maternity Hospital,
Birmingham

R. R. SAUNDERS

City Hospital,
Nottingham

- 1 Studd, J., *British Medical Journal*, 1973, 4, 451.

SIR,—In their paper (7 September, p. 606) Mr. W. A. Liston and Mr. A. J. Campbell raise important issues. Oxytocin is a neuro-secretion and it has been suggested that the normal concentration of both oxytocin and antidiuretin in the blood of a woman at term is of the order of 70-300 nU/ml blood. There is no evidence that the amount of oxytocin at the beginning of labour normally exceeds this figure in the blood of man, dog, cow, goat, or mare. If, therefore, oxytocin plays any role in labour in man it must be assumed that the myometrium becomes sensitive to that amount of oxytocin circulating in the blood. The intravenous infusion of 32 mU oxytocin/min (described by Mr. Liston and Mr. Campbell as "low") would, allowing for a half-life of 3-5 min, result in a concentration of exogenous oxytocin in the blood plasma of some 40,000 nU/ml. There is no reason to assume that such monumental amounts of oxytocin behave in a physiological manner and there is always the danger that the myometrial sensitivity to it increases while the amount of oxytocin infused is being doubled. Further, such amounts of oxytocin are likely to constrict placental blood vessels.

From the practical point of view low amniotomy per se induces labour in 80% of women at term $\pm$ 21 days and 60% of these are delivered within 12 hours. The hard core which cannot be delivered within 36 hours with the aid of a physiological drip is small. The crux of the whole matter

therefore is time, electronics, and fetal blood chemistry. In some circles the ultimate aim seems to be to cut the induction-delivery interval to 12 hours and virtually to close the labour ward at night. It is not clear in whose interest this time schedule is devised, whether that of the obstetrician, the midwife, the labour ward, or the hospital. Perhaps the great majority of women would welcome such a routine, but there is a minority of thinking women who dislike being treated as "battery hens" and this number may increase when it becomes known that this oxytocin assault is waged on 100% of women when only 20% fail to go into labour as the result of low amniotomy alone.

This glamorous development of a physiological process could be extended in Britain by significantly increasing the obstetric budget, but probably to not more than one-third of the obstetric units. It would not be applicable over vast areas of the Commonwealth in which we were once interested. There is already a ground swell of rumours concerning damage to uterus and cervix and it has yet to be shown that the clinical results so obtained are better than, or as good as, those achieved in the Dutch domiciliary midwifery service, which relies on selection of cases and on midwives rather than gadgets.

Perhaps the oxytocin sensitivity test¹ may be looked at again for Nixon and Smyth² suggested that amniotomy should not be done until the above test proved satisfactory. On the other hand, the belt transistor pulse generator³ ("electrical bikini"), either by itself or by potentiating "physiological" amounts of oxytocin, may prove to be the method of choice which will allow some option to the woman and allow induction to proceed in her own home.—I am, etc.,

G. W. THEOBALD

Eastbourne

- 1 Smyth, C. N., in *International Congress of Gynecology and Obstetrics*, p. 79. Basle, Sandoz, 1954.
- 2 Nixon, W. C. W., and Smyth, C. N., *American Journal of Obstetrics and Gynecology*, 1959, 77, 393.
- 3 Theobald, G. W., *The Electrical Induction of Labour*. London, Butterworth, 1973.

Oxytocin in Labour and Neonatal Jaundice

SIR,—We should like to present further data to support our contention (27 July, p. 228) that oxytocin during labour does not influence mean neonatal serum bilirubin levels.

In our original study 100 mothers received intravenous oxytocin infusion for a known length of time (dose in units of oxytocin was not recorded). Seventy-five mothers (group 1) had undergone induction by amniotomy followed by oxytocin and 25 mothers (group 2) received oxytocin to speed the progress of spontaneous labour. The table compares the mean neonatal serum

	Day 1	Day 6
Group 1 ..	1.5 $\pm$ 0.6	3.2 $\pm$ 1.7
Group 2 ..	1.4 $\pm$ 0.6	3.6 $\pm$ 1.6
	t = 0.21; N.S.	t = 0.93; N.S.

bilirubin levels in mg/100 ml ($\pm$ 1 S.D.) in these two groups on the first and sixth days of life, showing no significant differences. The birth weights were not significantly