LETTERS TO THE EDITOR

Randomised trial of early tapping in neonatal posthaemorrhagic ventricular dilatation: results at 30 months

EDITOR,—Recruitment to the randomised trial of early tapping in neonatal posthaemorrhagic ventricular dilatation closed in January 1987.[1 2] At that time, participating clinicians requested that the channels for randomisation remain open. They recognised that it would be some time before any information from paediatric follow up would be available to guide practice and argued that, in the meantime, the most ethical way to decide management was by random allocation. In consequence, a further 42 babies were randomised over the following 21 months: 22 to early tapping and 20 to conservative management. The groups randomised to the two policies were similar in their characteristics at trial entry. Overall, they were also very similar to those in the main trial in these respects, and also in terms of their neonatal management.

Six of the 42 children are known to have died before the age of 2 years (four in the early group). None of the 36 surviving children were lost to follow up. Information about the children was obtained from participating paediatricians. They completed a short, straightforward questionnaire, using the most recent information from hospital records, when the children were about 2 years old.

The table describes the overall outcome in terms of impairments with and without functional loss in the neuromotor and other domains. This is shown first, for this new cohort recruited after 31 January 1987, and then for the original trial cohort whose outcome has already been reported. The results are stratified by the presence or absence of a parenchymal lesion identified at trial entry.

No clear differences were detected between the randomised groups in either cohort. The estimated prevalence of functional loss among these 36 children (69%) was broadly similar to the rate among those in the main trial (79%). Impairment without functional loss was, however, more commonly identified in the main trial cohort than in the cohort followed up by questionnaire (12% and 0 respectively). The extra information from these 36 children increases the statistical power of the trial (that is, it reduces the standard error of the difference between the randomised groups). It does not, however, alter its main conclusion that there is no detectable benefit of early tapping.

The longer term effects of many perinatal interventions can only be judged reliably from information about the status in childhood of babies entered into randomised controlled trials as neonates or as fetuses. In large, often international, multicentre trials, a full paediatric assessment for all the children may simply not be feasible. In the posthaemorrhagic ventricular dilatation trial, a follow up using a simple questionnaire to paediatricians was less expensive and much easier to implement that the full assessment by a single developmental paediatrician in the children's home. The questionnaire approach seemed to perform well in identifying impairments with functional loss, although this conclusion must be cautious given the small number of children involved.

In contrast to the follow up by a developmental paediatrician, the questionnaire approach did not identify any children with neuromotor impairment, for example, tone or reflex changes, when there was no associated functional loss. Although it is possible that none of the children in this small sample had such impairments, it is more likely that the questions were not sensitive enough to detect neurological changes when not accompanied by functional loss at the age of 30 months.

This finding suggests that the questionnaire may need further refinement before it can be used with confidence in future large scale trials. The apparent insensitivity of the present tool to impairment without functional loss should not introduce any bias into the comparison *within* a randomised controlled trial, however (assuming that the questionnaire is applied in the same way in the two trial groups). Nor is there any evidence from this study that it does so; the conclusions from the two cohorts are the same. The potential advantage of a simple questionnaire approach to follow up is that any consequent loss of statistical power would be more than compensated if it was thereby possible to follow up substantially larger numbers of children and to identify substantially larger numbers of serious impairments.

Ideally, alternative strategies for the follow up of large randomised cohorts of children should be compared within the same group of children. We are therefore currently assessing the value of simpler alternatives (such as questionnaires to parents, health visitors, general practitioners) to a full paediatric assessment using data from a number of other perinatal trials within which we have incorporated parallel systems of assessment for each child.

Overall outcome; figures are number (%)

	Randomised after 31 January 1987			*Randomised before 31 January 1987 (and previously reported)*		
	Early tapping	*Conventional management*	*Total cohort*	*Early tapping*	*Conventional management*	*Total cohort*
All children:	*n=18*	*n=18*	*n=36*	*n=59*	*n=53*	*n=112*
Normal	7 (39)	4 (22)	11 (31)	5 (9)	5 (9)	10 (9)
Neuromotor impairment, no functional loss	0	0	0	7 (12)	7 (13)	14 (13)
Neuromotor impairment, functional loss	2 (11)	8 (44)	10 (28)	13 (22)	9 (17)	22 (20)
Single non-neuromotor impairment	2 (11)	0	2 (6)	2 (3)	1 (2)	3 (3)
Multiple impairment	7 (39)	6 (33)	13 (36)	32 (54)	31 (58)	63 (56)
Without parenchymal lesion at trial entry:	*n=9*	*n=7*	*n=16*	*n=25*	*n=19*	*n=44*
Normal	7 (78)	4 (57)	11 (69)	4 (16)	3 (16)	7 (16)
Neuromotor impairment, no functional loss	0	0	0	6 (24)	5 (26)	11 (25)
Neuromotor impairment, functional loss	1 (11)	3 (43)	4 (25)	1 (4)	3 (16)	4 (9)
Single non-neuromotor impairment	0	0	0	1 (4)	1 (5)	2 (5)
Multiple impairment	1 (11)	0	1 (6)	13 (52)	7 (37)	20 (45)
With parenchymal lesion at trial entry:	*n=9*	*n=11*	*n=20*	*n=34*	*n=34*	*n=68*
Normal	0	0	0	1 (3)	2 (6)	3 (4)
Neuromotor impairment, no functional loss	0	0	0	1 (3)	2 (6)	3 (4)
Neuromotor impairment, functional loss	1 (11)	5 (45)	6 (30)	12 (35)	6 (18)	18 (26)
Single non-neuromotor impairment	2 (22)	0	2 (10)	1 (3)	0	1 (1)
Multiple impairment	6 (67)	6 (55)	12 (60)	19 (56)	24 (71)	43 (63)

Relative risk (95% confidence interval) for multiple impairments: randomised after 31 January 1987: 1·17 (0·49 to 2·79); randomised before 31 January 1987: 0·93 (0·67 to 1·28); total trial: 0·97 (0·71 to 1·33).

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1 Ventriculomegaly Trial Group. Randomised trial of early tapping in neonatal posthaemorrhagic ventricular dilatation. *Arch Dis Child* 1990; **65:** 3–10.
2 Ventriculomegaly Trial Group. Randomised trial of early tapping in neonatal posthaemorrhagic ventricular dilatation: results at 30 months. *Arch Dis Child* 1994; **70:** F129–36.

Neonatal transport: safety and security

EDITOR,—The transfer of newborn babies for intensive care carries potential hazards not the least important of which is the risk of injury to baby or escorts in a road traffic accident. In a recent local incident the incubator was torn free of its mountings, the baby was thrown out, and escort personnel sustained significant injury.

Investigation revealed a number of 'design' faults which increase the likelihood of preventable injury and which we believe to be a feature of many neonatal transport systems throughout the country. Furthermore, the procedures for dealing with injuries caused by the accident were lacking and exacerbated the consequences. We suspect that many other units would encounter similar problems.

The methods for securing incubator systems into ambulances are inadequate. Simple side mounted (York Four) or floor (Bullhorn) fittings are used to hold stretchers. Incubators on stretchers compatible with one of these fittings cannot be carried in ambulances with the other form of stretcher mounting and vice versa. None of the current locking devices have been load tested (E Richardson, Northumbria Ambulance Service, personal communication), and our own experience suggests it is likely that they would allow heavy incubator systems to slip out with impact.

Incubator platforms are heavy. Neonatal transport systems when configured for intensive care weigh up to 150 kg. This carries a danger of injury to ambulance personnel when lifting and Health and Safety Executive guidelines now recommend personnel do not lift such heavy items unaided.[1] Such a payload also makes secure anchorage difficult and exacerbates the instability of the platform in the event of an accident.

No specific provisions to cover injuries sustained in such an accident were made by either the health service/NHS trust or the

ambulance service trust involved. By law the trust was liable for employees involved in accidents while on duty, but nevertheless the recourse to obtain compensation was through the courts with significant delays.

As a result of our experiences we have undertaken a comprehensive review of our neonatal transport operations. Initial problems of incubator security have been temporarily addressed with ring bolts set into the floor of ambulances which allow secure anchorage with cargo straps. Incubators are loaded using portable ramps. In the long term, in cooperation with our ambulance service, we have redesigned our transport system with a reduced payload around a no lift platform that will be compatible with all types of stretcher. The ambulance service has also undertaken to modify ambulance anchorages to accommodate newer stretcher types with transport incubators on board.

The standards of safety for neonatal transport incubators need to be reviewed. Attention needs to be given to reducing payload, and to the design of systems for loading and securing incubators within ambulances, whether road vehicle or aircraft. The problems of different incubators, ambulances, and stretcher designs can be avoided by using a universal mating platform. Each unit needs to be aware of its responsibilities to its staff regarding liability in the event of an accident.

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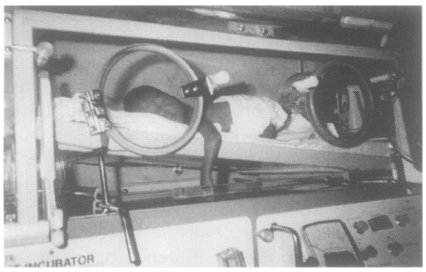
1 Health and Safety Executive. *Manual handling, guidance on regulations L23.* London: HMSO, 1992.

Unfriendly incubators

EDITOR,—Fractures in infants of very low birth weight (≤1500 g) not related to birth trauma are being recognised with increasing frequency.[1 2] These fractures are usually associated with bone demineralisation, which is frequently present in very low birthweight infants,[3] and almost two thirds of them involve the extremities.[1] Fractures in these infants can occur as the result of 'trauma' during physiotherapy or other procedures such as placement of intravenous lines.[1 4 5]

We have observed four infants with birth weights under 1000 g who sustained traumatic fractures of the extremities (one arm in three cases, one leg in the other), and we believe that the contributing factor was accidental trapping of the extremity by or under the plastic tray on which the mattress of the incubator lies. The fractures, diagnosed radiologically between 4 and 6 weeks of age, were associated with overlying bruising. Two of these babies also had well documented bone demineralisation. Subsequent to these independent observations in Athens and Montreal, we conducted a survey of incubators used in neonatal intensive care units and found that in many (even in some of the latest models) there was sufficient gap between the plastic tray and the incubator wall for an arm or a leg of the baby to slip between the incubator's wall and the plastic tray (figure). In many instances the nursing staff had tried to cover this gap with rolled sheets. In some incubators the tilting mechanism could not be securely locked at the desired tilted position



Incubator showing gap between plastic tray and wall allowing arm to be trapped.

and the plastic tray could therefore accidentally fall or jolt on the trapped arm or leg. Injury might also occur if the baby is pulled or turned by a nurse or a doctor unaware that a limb is trapped. The possibility that a fracture may be caused in this manner is enhanced if the bones are significantly demineralised.

The design of an incubator should be such that the plastic tray extends to the wall of the incubator such that any gap is too small for a baby's extremity to slip through and the tilting mechanism should be securely locked at the desired tilt. Incubators currently in use should be checked for this potential hazard.

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1 Koo WW, Sherman R, Succop P, *et al.* Fractures and rickets in very low birthweight infants: conservative management and outcome. *J Pediatr Orthop* 1989; **9:** 326–30.
2 Amir J, Katz K, Grunebaum M, Yosipovich Z, Wielunsky E, Reisner SH. Fractures in premature infants. *J Pediatr Orthop* 1988; **8:** 41–4.
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Excessive rates of asphyxia – acecdote or fact?

EDITOR,—It is well known that hypoxic ischaemic encephalopathy (HIE) in neonates is associated with adverse neurological outcomes.[1 2] The incidence of HIE can be a useful indicator of quality of intrapartum care provided to term infants,[3] while the severity relates to subsequent neurological outcome.[2] The Doncaster perinatal service has received much adverse publicity suggesting that their incidence of HIE was excessive ('Trial of labour', *World in Action*, Granada Television, 2 Nov 1992). We analysed data from the Trent Regional Neonatal Survey in order to establish if these criticisms were valid.

The Trent Regional Neonatal Survey collects data on all high risk babies admitted to perinatal units within the region. All babies greater than 35 weeks' gestation admitted because of HIE were included in this analysis. HIE was diagnosed using modified criteria of Levene *et al.*[2] Grade II HIE was defined as the infant having a history suggestive of asphyxia plus convulsions, while grade III was defined

The incidence of HIE in Trent perinatal units between 1990–3

Unit (deliveries /year)	No of babies with IHE: Grade II	Grade III	Total	Rate of HIE/ 1000 live births	95% Confidence interval
<3000					
1	1	4	5	0·58	0·24 to 1·42
2	4	0	4	0·98	0·13 to 7·24
3	7	8	15	1·8	1·07 to 3·02
4	14	5	19	5·1	3·22 to 8·07
5	14	4	18	3·0	1·87 to 4·81
3001–4500					
6	10	9	19	1·9	1·20 to 3·01
7	1	7	8	0·76	0·37 to 1·54
8	4	11	15	1·49	0·89 to 2·50
9	7	3	10	1·08	0·57 to 2·03
10	11	7	18	1·71	1·07 to 2·74
11	8	14	22	1·85	1·21 to 2·83
>4500					
12	13	8	21	1·53	0·99 to 2·37
13	16	8	24	1·53	1·02 to 2·30
14	12	8	20	1·16	0·74 to 1·81
15	7	9	16	1·1	0·67 to 1·81
16	12	17	29	1·73	1·20 to 2·40
Total live births (168 435)	141	122	263	1·56	1·38 to 1·76

as grade II plus the need for respiratory support. Data was collected by two independent visiting observers. The last three years of complete data were analysed (1 April 1990–30 March 1993).

There were a total of 168 435 live births in 16 perinatal centres (five subregional units and 11 smaller units) and 263 babies with HIE; 141 grade II and 122 grade III (table). The incidence of HIE for the region was 1·56 per 1000 live births (range 0·58–5·1 per 1000 live births). The Doncaster unit (number 6 in the table) had an incidence of 1·53 per 1000 live births – that is, similar to the region as a whole.

It is clear that criticisms levelled at this perinatal unit were unfounded and based on anecdotal evidence rather than fact. Data relating to HIE is not routinely collected by most perinatal units, however, we believe such data provide a valuable method of evaluating perinatal care. Only if the rate of HIE falls outside the 'normal range' is concern warranted.

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Diagnosis and management of non-immune hydrops in the newborn

EDITOR,—We read with interest the article by Stephenson *et al* on the diagnosis of non-immune hydrops in the newborn,[1] and we would like to emphasise that a wide range of inborn errors of metabolism (IMD) have been reported to be associated with non-immune hydrops and in many cases a feasible pathogenetic mechanism can be hypothesised.[2] As a cause of hydrops they are rare