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. 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 intervention 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 neonate and older children. 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 (fourfold) and 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 at 5 years. 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 be taken to 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 validity 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 had parallel systems of assessment for each child.

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 injuries, which in some cases are 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 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 lock-on devices have been 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 personnel when lifting and Health and Safety Executive guidelines now recommend personnel do not lift such heavy items unaided. Such a policy 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...
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Ann Johnson, Elizabeth Wincott, Adrian Grant and Diana Elbourne

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