J. Paediatr. Child Health (2005) **41**, 592–597

Routine neonatal postextubation chest physiotherapy: A randomized controlled trial

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Objective: To test the effects of a neonatal postextubation programme on the incidence of postextubation collapse and adverse outcomes.

Methods: A randomized controlled trial was carried out at the Mater Mothers' Hospital, Brisbane. Mechanically ventilated infants were randomized into one of two groups, physiotherapy group – which involved a regimen of chest wall percussion and oropharyngeal suctioning and control group – which involved suctioning without the percussion unless indicated. Chest X-rays were taken at 6 h and at 24 h postextubation. The primary outcome measure was postextubation collapse as determined by a paediatric radiologist blinded to the group allocation.

Results: One hundred and seventy-seven neonates were enrolled in the trial between 1997 and 1999. After an interim analysis, the trial was stopped early. No statistically significant difference was shown in the rate of postextubation collapse (15 of 87 (17.2%) physiotherapy group and 17 of 86 (19.8%) control group ($P = 0.85$)). No differences were shown between the groups in the number of apnoeic or bradycardic events, duration of requirement for supplemental oxygen or the need for re-intubation within 24 h postextubation.

Conclusion: The results of this trial suggest that a routine neonatal postextubation chest physiotherapy programme for all infants is not indicated. There was no evidence that chest physiotherapy is associated with any adverse outcomes.

Key words: physiotherapy; postextubation collapse; neonatal intensive care.

Postextubation collapse has been reported from neonatal intensive care units since the 1970s. The incidence of postextubation collapse has varied from 2.5% to 50%,[1–3] with re-intubation required in 10–30% of cases.[2] Putative factors reported for postextubation collapse include airway oedema and secretion retention. Decreasing birthweight,[3,4] duration of mechanical ventilation (MV), high oxygen concentrations, multiple intubations[5] and nasal intubation[6] have been reported as risk factors.

The presence of collapse may require increased support, such as additional oxygen, continuous positive airways pressure (CPAP), re-intubation for further MV, the need for respiratory physiotherapy and frequent suctioning. Furthermore, postextubation collapse may impact on the recovery phase thus prolonging the stay in hospital.

In 1979, Finer and Boyd reported a significant decrease in the incidence of postextubation atelectasis (collapse) following the implementation of a prophylactic chest physiotherapy programme consisting of positioning (with emphasis on drainage of the right-upper lobe), percussion and suctioning.[7] Other authors have recommended the use of physiotherapy in the periextubation period to prevent postextubation collapse.[3,7,8] Respiratory physiotherapy techniques, such as chest percussion and vibration are used to facilitate clearance of secretions,[9] thus improving lung volumes and oxygenation.[7,10] The application of percussion to ventilated infants before suctioning provided a protective effect against hypoxaemia that occurred during suctioning alone.[11]

Following the report of Finer and Boyd in 1979,[7] periextubation chest physiotherapy programmes were introduced into the majority of Australian neonatal nurseries.[12] However, with the introduction of surfactant, advances in methods of delivering MV, more frequent use of CPAP, together with improved humidification systems, questions have arisen regarding the benefits of routine chest physiotherapy postextubation.[13] Concerns have been expressed regarding the safety of percussion and vibration in the management of neonatal respiratory disorders. Reported complications of chest physiotherapy include hypoxaemia,[14,15] rib fractures[16] and associated brain lesions including intraventricular haemorrhage (IVH)[17] and encephaloclastic porencephaly.[18,19] The use of percussion, however, was shown to have no adverse effects on intracranial dynamics in preterm and term infants.[20] Furthermore, Beeby *et al.* found no evidence that chest physiotherapy was associated with abnormal neurological outcome in extremely preterm infants.[21]

A survey of all neonatal units in Australia and New Zealand was conducted to ascertain the use of postextubation physiotherapy programmes.[12] Forty per cent of all units in 1997 were using such a programme which involved the use of chest physiotherapy in the form of percussion and/or vibration, hence the conduct of a trial was considered to be of importance.

The present study was designed to test the hypothesis that a routine, prophylactic chest physiotherapy programme, defined as positioning, percussion and suctioning would reduce the incidence of radiographic evidence of postextubation collapse in neonates without increasing adverse outcomes, when compared with a programme of routine positioning and suctioning where infants received chest physiotherapy only when indicated.

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Accepted for publication 31 May 2005.

METHODS

The research protocol was approved by the Human Research Ethics Committee of the Mater Mothers' Hospital. Written informed consent was obtained from the parents of all infants before randomization.

Patients

The trial was carried out in the Intensive Care Nursery at the Mater Mothers' Hospital, Brisbane with the study population being recruited from infants who were mechanically ventilated from March 1997 to October 1999.

The study design was that of a single-centre randomized control trial. The infants being randomized by a computer-generated list of numbers placed in sealed envelopes. After extubation the next consecutive envelope was opened and the infant placed into one of two management groups – physiotherapy group and a control group. Infants remained in the same group for all subsequent extubations. Stratification was performed according to gestational age in three categories: ≤28 weeks, 29–36 weeks and ≥37 weeks gestation.

Infants were considered eligible to take part in the trial if extubation was planned following >24 h of MV. Infants were excluded if they were considered 'unstable' by the attending neonatologist or were both <1000 g and extubated <48 h of age (percussion is contraindicated in all infants who are less than 48 h of age if they weigh <1000 g), or had significant neurological signs of neonatal encephalopathy – stage 2 or 3[22] or had grade 3 or 4-IVH.[23] Any baby with radiologic osteopenia of prematurity or who was known to have rib fractures was also excluded.

Routine nursery care of ventilated infants at the time of the study included the following: orotracheal intubation, with a chest X-ray taken immediately after intubation to ensure optimal position of the tip of the endotracheal tube (ETT). Mechanical ventilation was provided using either a Drager Babylog 8000 or Bear Cub Ventilator with the Fisher and Paykel MR 700 respiratory humidifier for humidification. Routine ETT care was performed 4–6 hourly by instilling 0.25–0.5 mL of normal saline before suctioning by neonatal nurses or physiotherapists. After suctioning, the baby was changed and repositioned. The decision on timing of extubation was at the discretion of the attending neonatologist. In the case of significant deterioration following extubation, infants were re-intubated and MV was re-instituted, also at the discretion of the attending neonatologist. As a general rule, infants were re-intubated for indications upon which all neonatologists would agree; including increasing respiratory failure as shown by climbing CO_2, increasing O_2 requirements, recurrent apnoea and clinical judgement of excessive work of breathing.

Extubation procedure

Each infant was fasted for 4–6 h before extubation. After ETT suctioning, the baby was placed in the supine position. Three manual ventilated breaths were applied. At the end of the inspiratory phase of the third breath, the ETT was withdrawn. The oropharynx was suctioned and the infant placed in the prone position. In the event of an uncontrolled extubation, the oropharynx was suctioned and the infant placed in the $^1/_4$ prone position (right side uppermost) as per group allocation. If the infant was <1500 g or <30 weeks gestational age, CPAP was routinely applied. However, if any other infant was at risk of re-intubation, CPAP was also applied.

Postextubation management

Infants were positioned according to the positioning policy developed for all infants nursed in an incubator, that is, $^1/_4$ prone, nested and head increased. This programme was developed to encompass general principles of comfort, developmental and respiratory care for the preterm or sick neonate. In the $^1/_4$ prone position, the infant is placed $^1/_2$ way between prone and side lying. This provides the infant with the benefits of prone (calming and improved oxygenation) while minimizing the physiological and musculoskeletal effects of a full prone position (maximum lateral neck rotation and external rotation of hips and shoulders). This regimen of positioning and suctioning as required was followed for the remainder of the infant's stay in the intensive care nursery. All infants regardless of group allocation were nursed in these positions, alternating the side to which the baby faced.

Physiotherapy group

Infants randomized to the physiotherapy group received an active chest physiotherapy programme in the immediate postextubation period. These infants were placed in the $^1/_4$ prone position, with right side uppermost and chest percussion was applied using a Laerdal® infant resuscitation mask in the following manner: the index finger of one hand was placed over the top of the mask resulting in an effective seal and the mask held with the thumb and second finger. Percussion was then applied (using a wrist motion) to the chest wall with a pressure of no more than 5 cm H_2O. The guidelines for the pressure to be applied were decided by measuring the practice at the time. Three senior physiotherapists were asked to percuss an inflated anaesthetic bag, attached to a manometre using the same pressure that they would use on an infant. The reading for all physiotherapists was 5 cm H_2O. All staff including nurses were subsequently trained using this method. It was performed at a rate of 3/s for a period of approximately 1–2 min, with the physiotherapist watching the clock. During the treatment, the infant's head was stabilized by placing the other hand on the shoulders and head. Continuous monitoring of oxygen saturation, heart rate and blood pressure was recorded. Treatment was stopped if intolerance was observed. Intolerance was defined as an oxygen saturation reading of <85% for ≥4 s, or a heart rate of <100 bpm for ≥4 s. The procedure was carried out every 2 h for a period of 6 h commencing 2 h postextubation, followed on each occasion by suctioning of the naso/oropharynx and a change in position.

Control group

Control infants were placed in the $^1/_4$ prone position and given naso/oropharyngeal suctioning with position change every 4 h.

Infants in both groups had chest X-rays at 6 h postextubation and at 24 h according to routine nursery practice at that time. These chest X-rays were reviewed by the attending neonatologist. In the absence of collapse or consolidation, routine positioning and suctioning was continued. Those infants with collapse or consolidation were commenced on a chest physiotherapy regimen, which included percussion, regardless of treatment allocation. The decision to commence the targeted physiotherapy programme was made by the team of caregivers, which included the physiotherapist, nurse and neonatologist.

Outcome measures

The primary outcome measure was radiographic evidence of postextubation collapse (defined as lobar, segmental or subsegmental) on either the chest X-ray taken at 6 h or at 24 h postextubation. All chest X-rays were interpreted by a paediatric radiologist who was blinded to group allocation.

Secondary outcome measures included the use of reintubation and MV within 24 h of extubation; the number of infants with one or more episodes of apnoea within 24 h of extubation; duration of MV, duration of oxygen therapy and intracranial abnormalities detected at any point of time during the hospital stay or at follow up, including IVH, hydrocephalus, cystic periventricular leukomalacia (PVL) and encephaloclastic porencephaly. Infants were given oxygen therapy as required in order to maintain oxygen saturations between 85% and 96%. The diagnosis of intracranial abnormalities was made by cranial ultrasound performed according to routine policy in the unit. Infants born <1000 g had examinations on days 5–8 and day 21 of life and at 34–36 weeks postmenstrual age. Infants with birthweight of 1000–1500 g had examinations on days 5–8 and day 28 of life. One cranial ultrasound examination was performed on days 5–8 of life for infants >1500 g. More frequent scans were performed if clinically indicated, and as follow up of abnormal findings. Intraventricular haemorrhage was defined according to the classification described by Tudehope *et al.*[23] Grade 1-subependymal haemorrhage, grade 2-IVH filling <50% of the ventricle, grade 3-IVH filling >50% ventricle and grade 4-IVH with parenchymal involvement cystic PVL was defined as cystic changes detected in the brain parenchyma previously unaffected by IVH. Hydrocephalus was defined according to Levene as ventricular size >4 mm larger than the 97th centile, or hydrocephalus present that required a shunt or any form of drainage (permanent or transient).[24] Encephaloclastic porencephaly was defined as extensive cerebral destruction of unknown origin.[18]

Statistics and sample size calculations

It was estimated pretrial that for ventilated infants without an active physiotherapy programme there would be a 20% incidence of postextubation collapse. This estimate was based on previous reports.[3,4] We determined that a sample size of 430 infants (215 in each arm) would provide the study with 80% power with an alpha level of 0.05 to detect a 50% decrease in the primary outcome of postextubation collapse from 20% to 10% in the subjects who received the postextubation programme. A subgroup analysis of extremely preterm infants (gestational age <28 weeks) was planned. Data was analysed both for the first episode of extubation and all subsequent episodes of extubation. All infants randomized remained in the allocated study group for all subsequent extubations. An interim analysis was to be undertaken when half the study sample was achieved (215 infants). An independent data monitoring committee composed of a statistician, perinatal epidemiologist and a perinatal researcher was established.

Statistical analysis was performed using the software package STATA. Student's *t*-tests or Mann–Whitney *U*-tests were performed as appropriate for continuous variables and the χ^2 or Fisher's exact test for categorical data. Results were analysed on an intention to treat basis.

RESULTS

Between March 1997 and October 1999, 325 infants were assessed for eligibility. Fifty-one infants were deemed ineligible

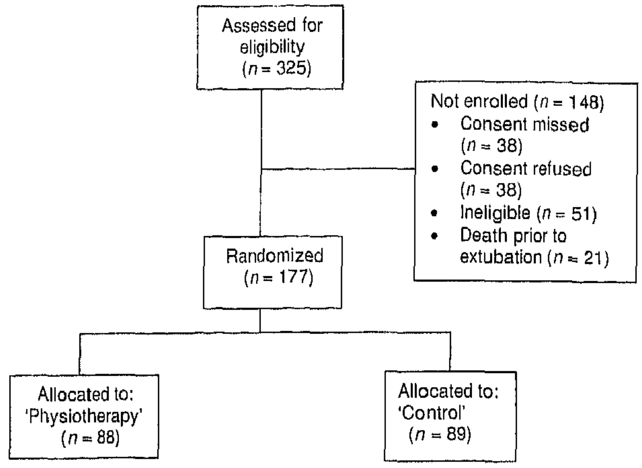

Fig. 1 Flow diagram of infants receiving mechanical ventilation assessed for eligibility.

with a further 21 infants dying before extubation. Of the 253 eligible infants, 177 infants (70%) were enrolled in the study. Consent was not obtained due to failure to approach or parental refusal for 76 infants. (Fig. 1).

An interim analysis was performed earlier than planned, after enrolment of 177 infants, due to concerns about the publication by Harding *et al.*, which suggested that chest physiotherapy in newborn infants was associated with major intracranial abnormalities detectable on ultrasound.[19] The analysis was undertaken by the independent data monitoring committee. No statistical difference was found between the two groups for the primary outcome measure of postextubation collapse and the projection was that there was little likelihood of detecting a significant difference with continued patient enrolment within the a priori calculated sample size. A decision was made to terminate the trial.

Eighty-eight infants were randomized to the physiotherapy group and 89 to the control group. The baseline clinical characteristics of birthweight, gestational age and weight at study entry not differ between the groups (Table 1). The majority of infants were mechanically ventilated for respiratory distress syndrome (93% in the physiotherapy group and 89% in controls), surfactant was also similar (82% in the physio group and 74% in the controls). In both groups, most extubations were planned

Table 1 Characteristics of enrolled infants

	Study group	
	Physio ($n = 88$)	Controls ($n = 89$)
Gestational age (weeks)		
Mean (SD)	30.1 (3.4)	30.5 (3.6)
<32, *n* (%)	60 (52.8)	57 (50.7)
<28, *n* (%)	15 (13.2)	17 (15.1)
Birthweight (g), mean (SD)	1450 (725)	1561 (758)
Weight on study entry (g), mean (SD)	1448 (719)	1541 (744)
Age at enrolment (days), mean (SD)	8.7 (8.6)	7.2 (7.8)
Reason for mechanical ventilation, *n* (%)		
Respiratory distress syndrome	82 (93.2)	80 (89.9)
Postoperative	4 (3.5)	3 (2.7)
Transient tachypnoea	1 (0.9)	4 (3.6)
Other	1 (0.9)	2 (2.2)
Exogenous surfactant, *n* (%)	74 (84)	64 (72)
Planned extubation, *n* (%)	80 (91)	82 (92)

Table 2 Postextubation collapse

	Study group			
	Physio (n = 88)	Controls (n = 89)	RR (95% CI)	P-value
Postextubation collapse – first episode of MV, n (%)	15/87 (17.2)	17/86 (19.8)	0.97 (0.67, 1.4)	0.85
<32 weeks, n (%)	9/60 (5.4)	8/59 (4.7)	1.11 (0.46, 2.67)	0.97
<28 weeks, n (%)	1/15 (6.7)	4/17 (23.5)	0.28 (0.04, 2.26)	0.33
All episodes of MV, n (%)	18/96 (18.8)	17/97 (19.8)	0.92 (0.61, 1.4)	0.67

MV, mechanical ventilation; RR, relative risk.

(91% in physiotherapy group and 92% in controls). There was no difference in the postnatal age at study entry.

Two hundred and twenty episodes of MV were analysed. Analysis was by first episode of MV and also by all episodes of MV. Table 2 shows the results for the primary outcome. Following the first extubation period, no statistically significant difference was observed between the groups with postextubation collapse occurring in 15 of 87 (17.2%) in the physio group and 17 of 86 (19.8%) in the control group. Similarly for all episodes of MV, no statistically significant difference was observed in the rate of postextubation collapse (18.8% in the physio group and 19.8% in the control group). No difference was observed in postextubation collapse in the subgroup analysis of infants <32 weeks gestation (nine of 60 (5.4%) in physio group and eight of 59 (4.7%) in controls). Although numbers are small, there was a trend towards reduction of postextubation collapse in the physio group for the subgroup of infants <28 weeks gestation (one of 15 (6.6%) in the physio group and four of 17 (23.5%) in the controls) (Table 2).

No differences were found between the groups for any secondary outcome measures including the number of infants with apnoeic episodes in the 24 h extubation, the use of re-intubation or oxygen requirements in the 24 h postextubation and the duration of oxygen therapy (Table 3). No difference was found between the groups in the incidence of IVH; ventricular dilatation or cystic PVL between the groups. No baby in either group had evidence of encephaloclastic porencephaly.

Death before hospital discharge was more frequent in the control group; however, this was not statistically significant (four out of 89 (4.5%) in the control group and one out of 88 (1.1%) in the physio group).

No differences were shown in any outcome measures for the subgroup of infants of less than 32 weeks gestation. In this subgroup, no difference was shown in the incidence of chronic lung disease diagnosed on the basis of an oxygen requirement at 28 days of age or at 36 weeks postmenstrual age (Table 4).

DISCUSSION

In this randomized controlled clinical trial, no statistical difference in the rate of postextubation collapse was found when comparisons were made between infants who received an active chest physiotherapy programme which involved percussion, positioning and suctioning and those who received routine positioning and suctioning without the percussion unless indicated. Furthermore, the results were similar on analysis of the results according to the first episode of MV and when all episodes of MV were taken into consideration. When the secondary outcomes were examined, there was no suggestion of benefit with regard to a reduced need for re-intubation, or duration of requirement for supplemental oxygen. Importantly, however, the active chest physiotherapy programme was not shown to be associated with any adverse outcome. Chronic lung disease, IVH or major cerebral abnormalities were not increased in the subgroup of infants <32 weeks who received the chest physiotherapy programme; however, this study is limited by small numbers of infants enrolled and the high loss to follow-up rate (25%) rendering interpretation difficult.

Almost 20% of the infants showed evidence of some degree of postextubation collapse. Although this may seem to represent a large number of infants, it is in keeping with the pretrial estimates and the results recently reported by others.[25,26] However, Davies and Cartwright reported a postextubation collapse rate of 2.5%, being much lower than all other previous reports.[1] The reason for their results being so dissimilar is unclear. The chest X-rays in the present study were interpreted in a blinded fashion by a paediatric radiologist. Accordingly, it may be that subtle changes of segmental or subsegmental collapse reported in our study would not have resulted in comment by others. In spite of radiographic findings, however, the clinical signs and oxygen requirements did not result a need for re-intubation for most infants, with only two (2.3%) in the physiotherapy group and three (3.4%) in the control group being re-intubated. All infants

Table 3 Secondary outcomes

	Study group			
	Physio (n = 88)	Controls (n = 89)	RR (95% CI)	P-value
Apnoea 24 h postextubation, n (%)	26 (30.0)	22 (24.7)	1.1.3 (0.82, 1.55)	0.47
Re-intubation within 24 h, n (%)	2 (2.3)	3 (3.4)	0.67 (0.11, 3.94)	0.99
Duration of oxygen therapy† – days median (interquartile range)	13 (6–56)	10 (6–35.5)		0.16
Duration of MV – days† median (interquartile range)	5 (3–14.5)	4 (3–8)		0.23
Intraventricular haemorrhage – grade 1 or 2	19	19	1.02 (0.58, 1.80)	0.92
Intraventricular haemorrhage – grade 3 or 4	0	0		
Major cerebral abnormalities‡	3	3	1.08 (0.22, 5.10)	0.74
Death before hospital discharge	1	4	0.25 (0.03, 2.22)	0.37

†Missing data: duration of oxygen therapy and duration of MV (physio: n = 86; controls: n = 88); ‡major cerebral abnormality defined as one or more of the following: cerebral cyst formation (porencephalic cyst, periventricular leukomalacia or encephaloclastic porencephaly) or hydrocephalus assessed at 6 weeks; missing data: major cerebral abnormalities (physio: n = 52; controls: n = 56). MV, mechanical ventilation; RR, relative risk.

Table 4 Secondary outcomes for infants <32 weeks gestation

	Study group			
	Physio ($n=61$)	Controls ($n=59$)	RR (95% CI)	P-value
Apnoea 24 h postextubation, n (%)	22 (36)	21 (36)	0.99 (0.69, 1.44)	0.98
Re-intubation within 24 h, n (%)	2 (3.3)	3 (5.1)	0.65 (0.11, 3.70)	0.62
Total duration of MV (days) – median (interquartile range)	7 (3–18)	5 (3–12)		0.26
Intraventricular haemorrhage,† n (%)	17 (28.3)	18 (30.5)	0.91 (0.52, 1.60)	0.95
Major cerebral abnormalities,‡ n (%)	2 (4.0)	3 (6.7)	0.60 (0.11, 3.43)	0.90
Chronic lung disease				
Chronic lung disease – oxygen requirement at 28 days, n (%)	33 (55.9)	26 (44.1)	1.26 (0.88, 1.81)	0.20
Chronic lung disease – oxygen requirement at 36 weeks postmenstrual age, n (%)	17 (28.8)	11 (18.6)	1.50 (0.77, 2.92)	0.23

†Intraventricular haemorrhage diagnosed up to 36 weeks postnatal age (data available for intraventricular haemorrhage – physio: $n=60$; controls: $n=59$); ‡major cerebral abnormality defined as one or more of the following: cerebral cyst formation (porencephalic cyst, periventricular leukomalacia or encephaloclastic porencephaly) or hydrocephalus (data available for major cerebral abnormalities – physio: $n=50$; controls: $n=45$); §data available for chronic lung disease – physio: $n=59$; controls: $n=59$. MV, mechanical ventilation; RR, relative risk.

found to have collapse on chest X-ray were commenced on chest physiotherapy programmes postextubation specifically designed for the area of collapse, as per routine neonatal nursery policy. Hence, this may well have promoted lung re-expansion and thus obviated the need for re-intubation in many instances.

Although numbers are too small to draw conclusions, there was a trend towards the physiotherapy providing a protective effect against collapse in the most immature (gestational age <28 weeks) group. If this were in fact true, one possible explanation may be that apart from the percussion being administered, the physiotherapy regimen also involved more frequent change of positioning and more handling by the staff which may have stimulated greater respiratory effort and improved ventilation and perfusion in this very immature group of infants. Before routine physiotherapy could be recommended for this group of infants, however, more information would be required.

We failed to show any difference in the use of re-intubation in the study groups. In the Cochrane review on the use of chest physiotherapy for prevention of morbidity in babies being extubated from MV,[13] on consideration of four trials (including this trial), there was a significant reduction (relative risk = 0.32, 95% CI = 0.13, 0.82) in the need for re-intubation within 24 h of extubation in the group of infants receiving an active physiotherapy programme. This result may not be exactly relevant, because the need for re-intubation was not objectively determined and also that the trial that found any significant difference was performed on a very different population.[6] The Cochrane reviewers also expressed caution in the interpretation of this result as the effect may not be generalizable to modern neonatal care as the reduction in re-intubation was due to the results of the trials completed in the 1970s and 1980s.[7,27] Accordingly, the evidence would suggest that routine chest physiotherapy in the postextubation period provides no benefit in terms of either reduction of postextubation collapse or the need for re-intubation. However, potential sources of bias in this study are that the treatments were necessarily unblinded and the important (although secondary) outcome measure of re-intubation was not predefined by protocol.

We examined the possibility of the chest physiotherapy programme resulting in adverse outcomes postextubation, especially in the area of neurological morbidity. Although small numbers of infants enrolled and missing data for the outcome of cerebral abnormalities does not permit a confident conclusion about the association of chest physiotherapy and major neurological morbidity, it was reassuring to show that no increase in the incidence of abnormalities on cranial ultrasound was shown. Importantly, no cases of encephaloclastic porencephaly were reported or described, this being a devastating condition associated with active chest physiotherapy in a study in New Zealand in 1998.[19] Our findings are in accordance with that of Beeby *et al.*, who also reported no case of encephaloclastic porencephaly in very preterm infants who received chest physiotherapy.[21] Furthermore, in that study, on follow up, no difference in the rates of cerebral palsy or in the mean development quotient was found between the infants who did and did not receive physiotherapy.

Of note, the group from New Zealand have published further analysis of the data surrounding the cases of encephaloclastic porencephaly and reported that the cluster of cases occurred at a time when the use of chest physiotherapy had decreased in comparison to earlier years when no cases were found,[28] and now suggest that neonatal chest physiotherapy 'is not inherently unsafe'.

Overall, it would seem that active chest physiotherapy in the neonatal unit is safe when applied judiciously.

Chest physiotherapy, as currently practised in the Mater Mothers' Hospital Neonatal Intensive Care Unit, comprises positioning programmes to prevent pooling of secretions, encourage optimal lung expansion and decrease the work of breathing. It may also include the use of percussion and vibration in the event of radiographic evidence of collapse caused by secretion retention. The decision to commence percussion is made by the clinical team, which includes the physiotherapist, neonatologist and nurse. Parents are informed of this decision at the next contact. Treatments are undertaken by physiotherapists in conjunction with the direct care nurses who have been trained by a senior physiotherapist.

The trial was terminated before the enrolment of infants calculated in the pretrial estimates. Nevertheless, our prospective, randomized controlled trial is the largest to date to examine the effects of a prophylactic chest physiotherapy programme in the prevention of postextubation collapse immediately postextubation for neonates. Analysis showed that if the differences observed persisted for the remainder of the trial, approximately 3500 patients would need to be recruited into each arm of the study, for statistical significance to be achieved. It would not have been feasible to increase the sample size to this degree.

In conclusion, the results of the present study indicate that a routine, active postextubation chest physiotherapy programme does not reduce the risk of postextubation collapse and that such a programme is not indicated. The results are generalizable for infants >1000 g and may only cautiously be applied to smaller infants. Although the numbers of infants studied are too small to be confident about rare important adverse effects of chest physiotherapy in this situation, it was re-assuring to find that we did not show that the programme was associated with any adverse short or longer term outcomes including apnoea or neurological morbidities. We suggest that, when clinically indicated, active chest physiotherapy applied in a judicious fashion may be used without risk of adverse outcome. We acknowledge that a great deal more work needs to be carried out in the area of neonatal chest physiotherapy before confident recommendations can be made.

ACKNOWLEDGEMENTS

We thank JP Kelly Mater Research Foundation and the Mater Hospitals Private Practice Trust Fund for the financial support provided to carry out the study. We also thank physiotherapists Megan Reading and Nadia Wilson and the neonatal nurses who assisted with the treatments, without whose cooperation and help, the study would not have been possible. We also thank Richard Hockey and James King for assistance with the interim analysis.

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