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Chest physiotherapy using passive expiratory techniques does not reduce bronchiolitis severity: a randomised controlled trial

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Abstract Chest physiotherapy (CP) using passive expiratory manoeuvres is widely used in Western Europe for the treatment of bronchiolitis, despite lacking evidence for its efficacy. We undertook an open randomised trial to evaluate the effectiveness of CP in infants hospitalised for bronchiolitis by comparing the time to clinical stability, the daily improvement of a severity score and the occurrence of complications between patients with and without CP. Children <1 year admitted for bronchiolitis in a tertiary hospital during two consecutive respiratory syncytial virus seasons were randomised to group 1 with CP (prolonged slow expiratory technique, slow accelerated expiratory

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flow, rarely induced cough) or group 2 without CP. All children received standard care (rhinopharyngeal suctioning, minimal handling, oxygen for saturation >92%, fractionated meals). Ninety-nine eligible children (mean age, 3.9 months), 50 in group 1 and 49 in group 2, with similar baseline variables and clinical severity at admission. Time to clinical stability, assessed as primary outcome, was similar for both groups $(2.9\pm2.1 \text{ vs. } 3.2\pm2.8 \text{ days, } P=$ 0.45). The rate of improvement of a clinical and respiratory score, defined as secondary outcome, only showed a slightly faster improvement of the respiratory score in the intervention group when including stethoacoustic properties (P=0.044). Complications were rare but occurred more frequently, although not significantly (P=0.21), in the control arm. In conclusion, this study shows the absence of effectiveness of CP using passive expiratory techniques in infants hospitalised for bronchiolitis. It seems justified to recommend against the routine use of CP in these patients.

Keywords Bronchiolitis · Chest physiotherapy · Passive expiratory flux · Clinical stability

Introduction

Viral bronchiolitis is usually a mild and self-limited disease [23], for which no pharmacological strategy was yet shown to be effective in reducing the length of hospital stay or the severity and duration of symptoms [4, 15, 26]. Consequently, the actual clinical practice guidelines consist of general supportive care, including minimal handling, nasal washings, oxygen and fluid replacement therapy when appropriate and sometimes bronchodilators [22, 25]. Similarly, current international recommendations do not advocate the routine



prescription of chest physiotherapy (CP) [3, 22, 25] partly because CP lacks scientifically proven clinical benefits and because it may cause complications such as rib fractures [5, 6] or worsening dyspnoea and hypoxaemia [28]. A recent updated Cochrane Review on the efficacy of "conventional chest physiotherapy" (cCPT), mainly vibration, percussion and postural drainage, in infants with acute bronchiolitis found no reduction in the length of hospital stay, oxygen requirements or clinical severity in the intervention group [19]. Nonetheless, other "new" techniques using passive expiratory manoeuvres to allow the mobilisation of secretions without airway collapse are nowadays routinely used in some regions of Europe [20] and were part of the French 2001 national consensus statement for the management of bronchiolitis in infants [24]. Only recently, the use of chest physiotherapy with passive expiratory techniques has been challenged and studied in bronchiolitis [10]. However, there is a lack of randomised studies addressing an evidence-based answer to this question.

The primary objective of this open randomised trial was to evaluate the effectiveness of CP techniques using passive acceleration of expiratory flux in reducing the time to clinical stability in infants admitted for acute bronchiolitis compared to infants not receiving CP. We also assessed the impact of CP on the daily improvement of a validated clinical and respiratory severity score and the occurrence of complications.

Materials and methods

Study population

Patients were recruited among children ≤ 1 year old admitted with the diagnosis of bronchiolitis during two consecutive respiratory syncytial virus (RSV) seasons (2005–2006 and 2006–2007). The start and the end of the RSV season were defined when ≥ 2 admissions were due to RSV infection during two consecutive 7-day periods and when ≤ 1 such admission occurred during two consecutive 7-day periods, respectively [11, 14]. Patients with comorbidities such as cystic fibrosis, neuromuscular disease or congenital heart disease, or patients admitted directly to the intensive care unit, were excluded from the study.

Patients were recruited by the participating physiotherapists (PL, CO, MB, HS, MF-B) or by the study physician (IR). Informed, signed consent was obtained from at least one parent. Randomisation was done by the attribution of a number contained in a sealed opaque envelope opened following the inclusion consent. Envelopes were prepared according to a randomisation list in blocks of random length (8, 10 or 12) by the study epidemiologist, not involved in the clinical phase of the study (TP).



This was a monocentric, open, randomised trial in infants hospitalised with bronchiolitis comparing the effectiveness of CP vs. no physiotherapy, in addition to the standard care for bronchiolitis. Our institution is not only a tertiary centre but also a primary care hospital as it is the only paediatric facility in the state of Geneva. This study was approved by the institution's ethical committee on clinical research in children (protocol 05-210).

Standards of care

All infants were treated according to the national and international recommendations for the care of infants hospitalised with bronchiolitis [22, 25]. Rhinopharyngeal suctioning after instillation of normal saline solution was applied to all patients if needed, as well as minimal handling, oxygen to achieve a saturation $(SpO_2) \ge 92\%$ and fractionated meals. Topical bronchodilators and steroids were not routinely used as they are not recommended in Switzerland. Nasal drops such as xylometazoline were often employed to decrease nasal congestion. Finally, antibiotics were administered when concomitant bacterial infection was suspected (prolonged fever, otitis media and increased white cell count).

All children underwent daily clinical evaluations at a fixed time point prior to the physiotherapy sessions when allocated to the group with CP. Evaluations were performed by a study physiotherapist who was different from the physiotherapist administering the treatment. Interobserver agreement among the five study physiotherapists for the evaluation score was excellent (kappa=1.0).

Experimental intervention (chest physiotherapy)

Patients assigned to the intervention group had two daily physiotherapy sessions provided by a physiotherapist not participating in the study at least 2 h after feeds to avoid abdominal discomfort. The following techniques were used [1, 8, 20, 24]:

- Prolonged slow expiratory technique (PSET) obtained by bimanual pressure over the thoracic cage and the abdomen, exerted at the start of the expiratory phase down to the residual volume and maintained for two to three respiratory cycles. This technique allows complete expiration in the presence of bronchial obstruction and facilitates drainage of the distal airways.
- Slow accelerated expiratory flow obtained by a manual pressure of variable strength, speed and length exerted over the thoracic cage at different lung volumes to optimise bronchial clearance of the proximal airways



 Induced cough achieved after a brief manual pressure over the trachea at the level of the suprasternal notch at the end of the inspiration (rarely used)

Outcome variables

Primary outcome

- Time to clinical stability, defined by feeding more than 50% of the required amount, the absence of vomiting, undisrupted sleep and SpO₂ ≥92% for more than 10 h
 Secondary outcome
- Change in clinical state, measured by a general score made of three well-being items (feeding, vomiting and quality of sleep)
- Change in respiratory state, measured by a respiratory score made of seven items (respiratory rate, SpO₂, presence and severity of retractions, adventitious respiratory sounds, presence of vesicular murmur, thoracic distension)

These scores, derived from existing literature [7, 9, 13, 27], correlate significantly, are strongly associated with the severity of disease and the number of days to clinical stabilisation (see on line section Table 1 and Fig. 1) and have high inter-rater reproducibility (kappa=1.0).

Occurrence of complications

Statistics

We first compared the groups at baseline for demographic and clinical characteristics. Categorical and continuous variables were compared between the groups. Dichotomous outcome variables were compared using Fisher's exact tests. Time to clinical stability was compared using Kaplan-Meier curves and the logrank test. This variable was also compared using a Student's t test. The level of significance for the tests was set at 0.05. The study was designed to detect a difference of a half standard deviation in time to clinical stability (estimated SD was 2 days based on previous hospitalisations, difference to be detected 1 day), with power of 90% and type one error of 5%. The calculated sample size was 80 patients in each arm. Changes in variables that were measured on a daily basis (general and respiratory score, SpO₂, respiratory rate) were examined in mixed linear models where daily observations were nested within patients. The model included the treatment group, the day of hospitalisation and an interaction term of treatment by day as fixed predictors. It included a patient-specific intercept and slope as random predictors. The treatment by day interaction captures the benefit of physiotherapy vs. control group in unit improvement per day. Analyses were performed using SPSS 17 software.

Results

Demographic data

A total of 103 children were randomised, 64 during the first winter season and 39 during the second season. Unfortunately, the second RSV season was very mild. Four children (one in the CP group and three in the control group) were subsequently excluded due to parental withdrawal of consent, erroneous initial diagnosis and direct admission to the intensive care unit or age (14 months). The 99 eligible children were evenly distributed between the CP arm (50) and the control arm (49).

The two groups were comparable at baseline, and there was no difference in clinical severity at admission as demonstrated by the initial clinical and respiratory score (Table 1). The administration of nebulised bronchodilators was similar between groups (38.0% vs. 40.8%, P=0.84) as was the proportion of children receiving nasal decongestant or oral antibiotics (64.0% vs. 69.4%, P=0.67 and 20.0% vs. 20.3%, P=1).

Clinical evolution

Primary outcome assessed by time to clinical stability (eating more than 50% of the required amount, the absence of vomiting, undisrupted sleep and $SpO_2 \ge 92\%$ for more than 10 h) did not differ significantly between the CP and the control group (2.9±2.1 days vs. 3.2±2.8 days, P=0.45; Fig. 1). Secondary outcomes, assessed by daily changes in clinical score (feeding, vomiting, sleep), in SpO_2 and in respiratory rate, were identical in the two groups. However, there was a slightly faster improvement reaching statistical significance for the daily changes in the respiratory score in the CP group (Table 2).

Occurrence of complications

Complications were defined as concomitant bacterial infection or transfer to the intensive care unit due to respiratory fatigue. Rescue CP was allowed in case of hypercapnia or need for nasal continuous positive airway pressure. Complications related to bronchiolitis severity were rare (n=19, 18%), but tended to occur more frequently in the control group without reaching statistical significance (12 vs. 7, P=0.21). No direct complications of CP such as respiratory deterioration occurred.



Table 1 Demographic and clinical severity data

	Physiotherapy	Control group	
	group (N=50)	(N=49)	
Sex M/F	27/23	28/21	
Age in days, means (SD)	110 (95)	108 (86)	
First episode of bronchiolitis	37/50 (74.0)	42/49 (87.5)	
History of eczema	4/50 (8.3)	3/49 (6.1)	
RSV ELISA positive (NPS)	37/50 (74.0)	37/49 (75.5)	
ELISA positive for other viruses	1/50 (2.0)	1/49 (2.0)	
	Means (SD)		
Clinical score	0.73 (0.91)	0.73 (0.96)	
Respiratory score	9.5 (3.6)	9.1 (3.6)	
Respiratory rate	53.2 (12.7)	51.2 (11.3)	
Oxygen saturation (SpO ₂)	91.9 (4.5)	92.4 (4.8)	
Capillary blood pH	7.37 (0.06)	7.37 (0.05)	
Capillary pCO ₂ (kPa)	5.73 (1.72)	6.11 (1.30)	
Bicarbonates (mmol/l)	23.1 (2.5)	24.3 (2.1)	

Results are expressed as n/n for sex, mean (SD) and n/N (%) RSV respiratory syncytial virus, NPS nasopharyngeal swabs

Discussion

This open randomised study assesses the efficacy of CP using passive expiratory techniques for the care of infants hospitalised for bronchiolitis. It does not show significant clinical benefits of daily CP compared to no CP in addition to simple rhinopharyngeal suctioning. In particular, the primary outcome of time to clinical stability was not significantly different between the groups. Of the secondary outcomes, analysed separately in order to better distinguish the impact of CP on respiratory items and general items, neither the respiratory rate nor the SpO₂ improved more rapidly in the CP group, but the daily changes of the respiratory score were slightly faster though the difference was not major in clinical terms.

In diseases with impaired mucociliary clearance such as cystic fibrosis, CP has been shown to improve bronchial mucus transport [12]. In viral bronchiolitis, characterised by inflammation, oedema and necrosis of epithelial cells lining small airways and increased mucus production, CP could theoretically be efficacious in helping the clearance of airway secretions. However, studies using cCPT (vibration and percussion with postural drainage) have not shown any benefit on the severity of the clinical score, including oxygen requirements and length of hospital stay, in patients

receiving cCPT compared to controls [19]. In Frenchspeaking Europe, these techniques have largely been replaced by ones using passive expiratory manoeuvres such as PSET [1, 8, 20]. These techniques avoid a high transmural pressure and allow the mobilisation of secretions from the more distal airways [17]. Despite its widespread use, only one study published in an abstract form showed a statistically significant decrease in severity score, SpO2 and heart rate after physiotherapy using PSET and induced cough [21]. Conversely, our work did not show a significantly faster improvement in the severity score assessed through general well-being items such as feeding, vomiting or sleep in the group with CP or in the respiratory rate and SpO₂ evaluated separately. There was however a slightly significant decrement in the respiratory score composed of all items (presence and severity of retractions, auscultation, hyperinflation, respiratory rate and SpO₂) that we explain by the change in adventitious sounds following a CP session due to the displacement of secretions. Most of all, our study using passive expiratory techniques did not reduce the time to clinical stability, defined by feeding more than 50% of the required amount, the absence of vomiting, undisrupted sleep and SpO₂ \geq 92% for more than 10 h in the intervention group. Likewise, a multicentre, randomised

Table 2 Daily changes (unit per day) in outcome indicators using mixed linear models

	Physiotherapy group	Control group	P
Clinical score (points/day)	-0.12 (-0.08 to -0.15)	-0.09 (-0.06 to -0.13)	0.37
Respiratory score (points/day)	-1.6 (-1.4 to -1.8)	-1.3 (-1.1 to -1.5)	0.044
Oxygen saturation (%/day)	1.0 (0.7 to 1.2)	1.0 (0.8 to 1.2)	0.85
Respiratory rate (rate/day)	-1.1 (-0.6 to -1.7)	-0.7 (-0.2 to -1.2)	0.24

(95% confidence interval)



trial conducted in France [10] found no significant effect of CP on time to recovery, defined by a shorter time without oxygen supplementation, the absence of chest recession and adequate feeding, in the intervention group. Both these randomised trials seem to confirm that interventions such as CP do not accelerate the natural evolution of bronchiolitis, a self-limited disease in the majority of cases. Thus, conclusions derived from percussion and vibration techniques [2, 16, 19, 28] can also be applied to techniques using passive acceleration of expiratory flux mainly because the inflammatory response has the greatest impact on severity of bronchiolitis and cannot be relieved by physical measures [18, 22, 23].

Interestingly, patients in the physiotherapy group tended to have fewer complications even if they occurred less frequently than generally described [29]. This difference cannot be attributed to a higher initial severity of disease and is difficult to explain. We cannot exclude that in cases with a severe course, CP might delay or prevent the need for supportive ventilation. However, the number of complications of bronchiolitis was scarce and could not be analysed separately. Contrarily to the study from Gajdos et al. [10], where they experienced an increased proportion of respiratory destabilization or vomiting in children during CP procedure, we did not observe direct complications of CP. This might be explained by our strict timing of CP sessions long after feeding.

The lack of blinding of this open study was overcome by separating the evaluations and the interventions. One physiotherapist carried out the clinical evaluation at a fixed time point prior to the physiotherapy sessions in the CP group, and another physiotherapist performed the daily treatments.

It is important to recall that only hospitalised patients were recruited, representing a minority of children with bronchiolitis. Thus, our observations cannot be extended to outpatients without further work.

In conclusion, this study shows the absence of effectiveness of CP techniques using passive acceleration of expiratory flux in infants hospitalised for bronchiolitis. It seems justified to recommend against the routine prescription of CP, as already proposed by some consensus conferences [25]. This important finding should be included when establishing allocation of resources in the actual cost-containment era. Further work is needed before extending this recommendation to children managed on an outpatient basis.

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Conflicts of interests None to declare.

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