Bronchial Clearance Physiotherapy in Pediatrics. A Controlled, Randomized, Multicenter Study of the Short-Term Effects on Respiration during Outpatient Care for Infants with Acute Bronchiolitis

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Abstract

Objectives The use of chest physiotherapy (CP) has not, to date, been shown to be effective in the care of infants hospitalized for bronchiolitis. However, it has not yet been studied in outpatient settings. The aim of our study was to examine the short-term benefit of CP with the increased exhalation technique (IET) on the respiratory conditions of nonhospitalized infants.

Methods Our research consisted of a multicenter, randomized, controlled, single-blind study of infants under 1 year old. A decrease in the severity score of the infants' respiratory condition was compared between two groups: one receiving CP and one without CP. Eighty-two infants were randomized: 41 in the CP group and 41 in the control group. Blinded assessors determined the Wang Clinical Severity Score at inclusion (T0) and 30 minutes later (T1) for each group.

Results Improvement in the severity score was observed for 29 infants (70.7%) in the group receiving CP, compared with 4 infants (9.76%) in the control group ($p < 0.001$). The mean decrease in the Wang Clinical Severity Score was -2 (± 1.32) in the group receiving physiotherapy compared with -0.22 (± 0.99) in the control group ($p < 0.001$).

Conclusion For outpatient care of infants with bronchiolitis, the results of this study suggest that CP with IET leads to a short-term improvement of mucus airway obstruction parameters.

Keywords
- respiratory viruses
- bronchiolitis
- infants
- chest physiotherapy
- primary health care

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Introduction

In every part of the world, bronchiolitis is common among infants and leads many parents to seek medical care and physiotherapy in outpatient settings. Several studies and international recommendations[1–3] have found that there is no effective drug to treat a first episode of bronchiolitis.

Chest physiotherapy (CP) techniques including postural drainage therapy, vibration, and conventional chest physiotherapy (CPT) are not considered to be effective,[4,5] even if some exhalation techniques, like increased exhalation technique (IET), seem to provide immediate and transitory relief for infants with moderate exhalation difficulties.[6] The authors of the most recent Cochrane Review recommended testing the potential effect of exhalation techniques among mildly to moderately affected nonhospitalized patients. The studies that have evaluated the effects on airflow have primarily been interested in a patient population of hospitalized infants.[7–9] Recently in France, the National Health Authority has called for randomized "ambulatory" studies to be conducted to evaluate such techniques which remain rather widely prescribed by doctors,[9] given that, to date, the amount of evidence from studies in outpatient settings (private practice) was deemed to be insufficient.[10–12]

From a pathophysiological perspective, the respiratory symptoms of infants with bronchiolitis are the consequence of bronchial obstruction due to inflammatory swelling (edema) of the small airways, with the accumulation of mucus and cellular debris secondary to respiratory necrosis caused by the virus.[13] Coughing, which only impacts the first bronchial divisions, is the only way that infants have to clear the airways of mucus. Previous modeling-based studies[14,15] have shown how CP techniques to modulate exhalation flows could affect the entire airway tree by increasing the pressure that air exerts on the mucus during exhalation and by immediately reducing hydrodynamic resistance.[14]

This background leads to put forward the hypothesis that CP would improve the mucus airway obstruction parameters of children receiving care in outpatient settings.

Materials and Methods

Study Design and Implementation

We conducted a multicenter, randomized, controlled, single-blind study comparing a group of infants receiving physiotherapy and a control group with no physiotherapy. Four centers of investigation contributed to the enrolment of patients: two in the Ile de France region, one in Normandy, and one in the Auvergne Rhône Alpes region. The study was conducted during an acute bronchiolitis epidemic season between December 17, 2016, and February 1, 2017.

After consulting the Committee for the Evaluation of the Ethics of Research Projects at the Robert Debré University Pediatric Hospital Centre, we followed its recommendation and submitted our study to an institutional review board (the Committee for the Protection of Persons [CPP]). The "CPP IV Ile de France" approved the study on November 22, 2016. We also registered this clinical trial at the French National Agency for Medicines and Health Products Safety (ANSM) under the reference ID-RCB 2016-A01553–48 and submitted a declaration of compliance with a reference methodology to the French Data Protection Authority (CNIL). The parents of all participating infants received written information about the study. They gave their informed oral consent and did not oppose their children taking part in the study.

Participants

To be eligible, infants had to be from 1 to 12 months of age,[16] presenting a first or second episode of bronchiolitis for which their general practitioner had prescribed outpatient CP (the first or second session of CP for this episode). Only infants with a score of $\geq$4 and $<$9 on the Wang Clinical Severity Scoring System were randomized after inclusion.[17] Children born prematurely before 34 weeks' gestation and those with a history of bronchopulmonary dysplasia and serious pulmonary or cardiac disease were excluded. Children presenting a contraindication to CP with IET (prolonged corticosteroid therapy, rickets, osteogenesis imperfecta, or rib fracture) were also excluded from the study.

Randomization

For randomization into blocks which were stratified by center and centralized, an on-line system (PHP/MySQL) was made available for the study by the Clinical Research Centre (CRC) of the Créteil Intercommunal Hospital Centre. An investigator authorized to perform enrolment of children used a log-in name and personal password to connect to the system. Randomization was performed after confirming that inclusion criteria had been met and that no exclusion criteria were present.

To ensure balance among the groups within each study center, a stratification-by-center approach was used. To avoid any selection bias concerning a specific center, an upper limit was set at 40 patients per center. A 1:1 allocation with set blocks of four was used. Study participants were randomized to the group receiving CP immediately (group A) or to the control group receiving delayed CP (group B). For group A, the Wang Clinical Severity score was measured just after the CP session. In group B, the Wang score was measured 30 minutes after randomization. The infant remained alone with his or her parents without any therapeutic intervention until the delayed CP session.

Conduct of the Study

After informing the parents and obtaining informed consent, the authorized investigator enrolled the infants meeting inclusion criteria (►**Fig. 1**). The Wang Clinical Severity scores were measured at inclusion (T0) and 30 minutes after inclusion (T1) by two different blinded assessors. For participants in the study arm who received CP, conditions were arranged, so that the assessor would not know which randomization arm the infants were assigned to. Parents were instructed that verbal exchanges with the assessors would not be possible. The randomization arm was obtained by entering the investigator's initials and the randomization site. Only the investigator physiotherapist who enrolled the child in

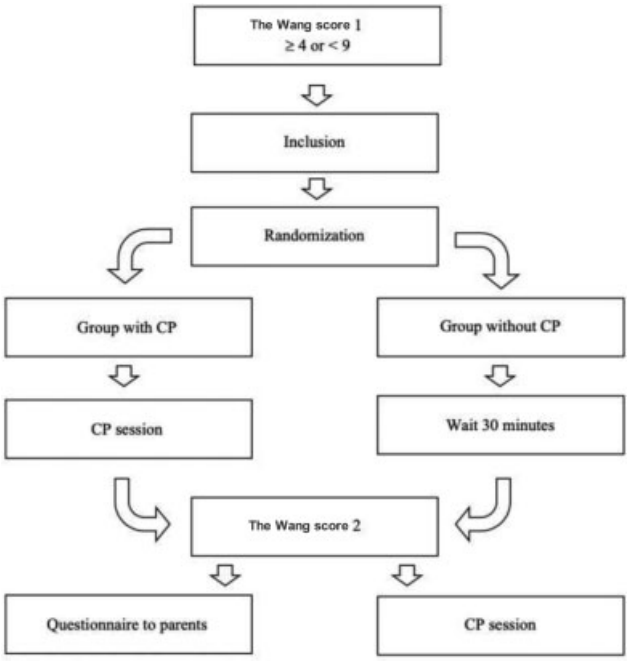

Fig. 1 Study design. CP, chest physiotherapy.

the study and the physiotherapist who performed CP with IET knew which group each participant had been assigned to, for the children randomized to the CP group. The reason for this sequenced evaluation, independent of the Wang scores, was to avoid any observer bias while also relying on the satisfactory interobserver reproducibility of the score[18–20] and its utilization for studies involving hospitalized infants.[21,22] The standard of care was respected, and all infants participating in this study received CP with IET.

Intervention

The physiotherapists/investigators in our study, all received university training in pediatric CP and were trained prior to taking part in the study, consistent with the standardization of professional practices. The study involved practicing CP with a passive technique for sufficient airflow to generate air–mucus interaction during exhaling by using differentiated volumes and airflow. The increase in airflow takes place at different pulmonary volumes to discern the location of air/mucus interaction.[15] To monitor expiratory airflow, two clinical indicators were used: an audible indicator (an increase in wet or productive coughing sounds) and a tactile indicator (vibrations under the hand on the thorax).[23] Using both indicators guides the physiotherapist's movements. The increase in expiratory airflow is caused by manual thoracic-abdominal pressure that respects the mechanical rotational axis of the costovertebral and costotransverse joints.[11]

The anatomy of infants' lower airways is associated with poor pulmonary compliance which means that the movements with each expiration must be carefully controlled to obtain a continuous flow without causing the collapse of the peripheral bronchial structure.[11] As long as the flow can be heard from the infant's mouth and the expiratory movement can be performed, collapsing does not occur.[11] When the technique is performed correctly under the appropriate safety conditions, it is intended to drain the secretions and reduce the obstructive syndrome causing congestion. From a physical viewpoint, airflow augmentation techniques increase the zone of constraint on the mucous to a degree that is sufficient to mobilize it and to decrease the airway tree's hydrodynamic resistance.[14]

Primary Endpoint

A comparison of the number of responsive patients within each group was our primary endpoint. A child was considered to be responsive when the grading of clinical severity (the Wang score) decreased between the first and the second assessments.[17] In outpatient practice, when monitoring symptoms, this is more relevant than a change in the baseline score.[24] The Wang Clinical Severity score[17] assesses the intensity of breathing difficulty in infants (►**Table 1**). A global score of less than or equal to 3 of 12 indicates benign respiratory difficulty; score between 4 and 8 of 12 signifies moderate respiratory difficulty; and score 9 of 12 or more signifies severe respiratory difficulty.[18] Patient and control group oxygen saturation values have not been added to the pre- and post-CP assessments. In fact, our protocol was intended to comply that the routine ambulatory care usually performed. Grading was blinded and was performed by assessors who were physiotherapists. They were not aware of which randomization group each patient had been assigned to.

Table 1 The Wang score

	Score			
	0	1	2	3
Respiratory rate (breaths/min)	<30	31–45	46–60	>60
Wheezing	None	Terminal expiratory or only with stethoscope	Entire expiration or audible during expiration without stethoscope	Inspiration and expiration without stethoscope
Retractions	None	Intercostal only	Tracheosternal	Severe with nasal flaring
General condition	Normal	–	–	Irritable, lethargic, and poor feeding

Secondary Endpoints

- For each group, changes in the Wang Clinical Severity score assessed at T0 and at T1 following randomization.
- Tolerance of the CP session in group A, based on the patient's reaction to CP: discomfort, vomiting, pain, and behavioral changes.

Data

We collected data concerning but not limited to identification of an atopic predisposition,[25,26] infants' age, concomitant treatments, and data entered by the physiotherapist/investigator in the electronic case report created for the study.

Statistical Analyses

The Association Clinique Thérapeutique Infantile du Val de Marne (ACTIV) was in charge of managing data and processing statistics.

Qualitative variables were expressed in absolute values and percentages, while quantitative variables were expressed in mean and standard deviation. The two groups were compared using the Chi-square test, Fischer's exact test, Student's *t*-test, or the Wilcoxon's and Mann–Whitney tests, according to the type and distribution of the variables. Matched datasets, before and after intervention, were analyzed using paired Student's *t*-tests or McNemar's test, depending on the type of data. The significance level was $p < 0.05$. For statistical analyses, STATA v13.1 software (Stata Corporation, College Station, Texas, United States) was used.

Results

Characteristics of the Study Population

A total of 190 infants were seen in the four participating centers (►**Fig. 2**) during the study period. Eighty-two infants were enrolled, with 41 in the CP group (group A) and 41 in the control group (group B). Within each group, the patient populations were comparable in age and gender. The mean patient age was 204.8 days (±82.4) in group A and 218 days (±81) in group B.

There was a higher percentage of male infants in group A (61%) and in group B (56.1%). Other demographic characteristics were collected at inclusion for which statistical tests revealed no differences in distribution (►**Table 2**). Finally, no significant differences were observed between the two groups as concerns as the number of days the disease progressed following randomization.

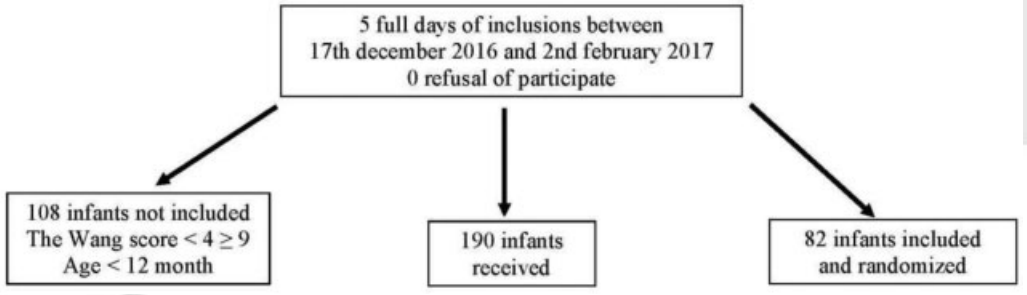

Fig. 2 Flow chart.

Table 2 Characteristics of the study population

Item	Group A ($n = 41$)	Group B ($n = 41$)	*p*-Value
Age (d)	204.8 (±82.4), 198 [55; 363]	218 (±81), 219 [79; 364]	0.47[a]
Sex (male)	25 (61%)	23 (56.1%)	0.65[b]
Family history of asthma	10 (24.4%)	16 (39%)	0.15[b]
History of eczema	3 (7.3%)	5 (12.2%)	0.71[c]
No treatment	15 (36.6%)	18 (43.9%)	0.50[b]
Antibiotic treatment	10 (24.4%)	7 (17.1%)	0.41[b]
Bronchodilator treatment	21 (51.2%)	20 (48.8%)	0.83[b]
Corticosteroid treatment	7 (17.1%)	11 (26.8%)	0.29[b]
Antitussive treatment	1 (2.4%)	1 (2.4%)	1.00[c]
Delay between symptoms and the session (d)	7.9 (±7.1), 6 [1;29]	4.8 (±3.4), 4 [1; 17]	0.01[a]
			0.03[d]

[a]Student's *t*-test.
[b]χ^2 test.
[c]Fisher's exact test.
[d]Wilcoxon's/Mann–Whitney test.

Table 3 The Wang score variation in the two groups

	First assessment			Second assessment		
Student's test	Group A T0 ($n=41$)	Group B T0 ($n=41$)	p-Value	Group A T1 ($n=41$)	Group B T1 ($n=41$)	p-Value
Wang score	4.83 ($\pm$0.86), 5 [4; 7]	4.83 ($\pm$0.99), 5 [4; 8]	1	2.83 ($\pm$1.16), 3 [1; 6]	4.61 ($\pm$1.18), 4 [2; 8]	<0.001

Table 4 Comparing the Wang Clinical Severity score variations in groups A and B

	Group A (with chest physiotherapy)		($n=41$)		Group B (no chest physiotherapy)		($n=41$)	
	0–3 (%)	4–8 (%)	9–12 (%)		0–3 (%)	4–8 (%)	9–12 (%)	p-Value
0–3	0 (0.0)	0 (0.0)	0 (0.0)	0–3	0 (0.0)	0 (0.0)	0 (0.0)	
4–8	29 (70.7)	12 (29.3)	0 (0.0)	4–8	4 (9.76)	37 (90.24)	0 (0.0)	<0.001
9–12	0 (0.0)	0 (0.0)	0 (0.0)	9–12	0 (0.0)	0 (0.0)	0 (0.0)	

Study Findings

Following the first CP session, 29 infants (70.7%) in group A were responsive to CP with IET, measured by a change in the classification of the severity of their condition, compared with four infants (9.76%) in the control group ($p<0.001$; ►**Table 3**). A significant change in the results of the Wang Clinical Severity score (secondary endpoint) at T0 and T1 was also observed between the two groups: for group A, from 4.83 ($\pm$0.86) to 2.83 ($\pm$1.16) and for group B, from 4.83 ($\pm$0.99) to 4.61 ($\pm$1.18; ►**Table 4**). The mean decrease in the score was -2 ($\pm$1.32), -2 [-5; 0] in group A compared with -0.22 ($\pm$0.99), 0 [-3; 1] in group B ($p<0.001$).

Variations in the Wang Score Items for Each Group

In group A, between T0 and T1, respiratory rate and wheezing were the most impacted factors in the Wang Clinical Severity score (►**Tables 5**, **6**). For "respiratory rate," a score of 2 was assigned to 29 infants (70.7%) before the CP session, and to none after the CP session. For "wheezing," a score of 2 was assigned to 22 infants (53.7%) before the session and to 8 infants (19.5%) after the session. For the item "draw": 20 infants (48,7%) before the CP session and 9 infants (22%) afterward.

Adverse Events

No adverse events were reported among the infants in group A during this study.

Discussion

Previously, the impact of CP with IET on respiration had not been studied using randomization with a control group for outpatient care to treat acute bronchiolitis in young infants. This is therefore a first study that focuses on a patient population of infants with moderate forms of bronchiolitis. The study was unable to recruit a satisfactory number of infants in each group, while also limiting observer bias. The physiotherapists who acted as assessors were independent; they were not the same physiotherapists who provided CP. Our study population was representative of infants with bronchiolitis as described in the literature, with respect to gender and age (under 12 months).[16] This is a study population that requires outpatient care with the Wang Clinical Severity score of between 4 and 8. The interobserver reproducibility of the score is moderate, according to the classification by Landis and Koch (kappa = 0.48).[19,20] In addition, it has been used many times in studies to evaluate the effects of CP.[21,22]

Our findings revealed that the grading of the participating patients' initial respiratory difficulties changed significantly, becoming less severe, between the first and second assessments (►**Table 4**). This change must be associated with variations in the Wang score (►**Table 3**). In light of the study population's characteristics (►**Table 2**), the clinical improvement observed during care would seem to be statistically unrelated to age, the presence of an atopy or treatment with prescribed medication, regardless of adherence. It appears to suggest that CP with IET has a short-term effect on the evolution of respiratory parameters associated with bronchiolitis, in particular airway obstruction syndrome. In our study, we observed a variation in all the items identifying bronchial obstruction. Variation in the three items simultaneously indicated a reduction in the infants' respiratory difficulty (►**Table 6**). Those outcomes could not be corroborated by an improvement in oximetry parameters as our study only evaluated clinical parameters collected in the Wang score. Otherwise, investigators study, whether food intake in the preceding 24 hours, could serve as an indicator of hypoxia in infants with bronchiolitis.[27]

IET taken in isolation may impact the airway tree hydrodynamic resistance caused by hypersecretion and its rheological transformations,[14,15] the latter being one of the three causes of airflow obstruction observed in bronchiolitis, which also include inflammation and potential bronchial hyperreactivity.[13,26] The reduction of airway tree hydrodynamic resistance could explain the short-term clinical

Table 5 Variation in the Wang score items between T0 and T1 for groups A and B

	The first Wang score			The second Wang score		
Item	**Group A T0 ($n=41$) *n* (%)**	**Group B T0 ($n=41$) *n* (%)**	**Item**	**Group A T1 ($n=41$) *n* (%)**	**Group B T1 ($n=41$) *n* (%)**	***p*-Value**
Wang score			0.630			0.000
1	0 (0)	0 (0)		5 (12.2)	0 (0)	
2	0 (0)	0 (0)		12 (29.3)	2 (4.9)	
3	0 (0)	0 (0)		12 (29.3)	2 (4.9)	
4	17 (41.5)	20 (48.8)		10 (24.4)	17 (41.5)	
5	16 (39)	11 (26.8)		1 (2.4)	12 (29.3)	
6	6 (14.6)	8 (19.5)		1 (2.4)	6 (14.6)	
7	2 (4.9)	1 (2.4)		0 (0)	1 (2.4)	
8	0 (0)	1 (2.4)		0 (0)	1 (2.4)	
Respiratory rate			0.239			0.000
0	1 (2.4)	0 (0)		26 (63.4)	10 (24.4)	
1	9 (22)	12 (29.3)		15 (36.6)	26 (63.4)	
2	29 (70.7)	23 (56.1)		0 (0)	5 (12.2)	
3	2 (4.9)	6 (14.6)		0 (0)	0 (0)	
Wheezing			0.128		0 (0)	0.003
0	4 (9.8)	1 (2.4)		19 (46.3)	6 (14.6)	
1	13 (31.7)	21 (51.2)		14 (34.2)	16 (39)	
2	22 (53.7)	19 (46.3)		8 (19.5)	19 (46.3)	
3	2 (4.9)	0 (0)		0 (0)	0 (0)	
Tirages			0.054			0.005
0	5 (12.2)	0 (0)		18 (43.9)	5 (12.2)	
1	16 (39)	22 (53.7)		14 (34.2)	19 (46.3)	
2	20 (48.7)	19 (46.3)		9 (22)	17 (41.5)	
3	0 (0)	0 (0)		0 (0)	0 (0)	
General condition			1.000			0.494
0	39 (95.1)	39 (95.1)		41 (100)	39 (95.1)	
3	2 (4.9)	2 (4.9)		0 (0)	2 (4.9)	

improvement on the Wang Clinical Severity score, based on respiratory rate, wheezing, and labored breathing.

The fact that no adverse events were reported would appear to confirm the observations of two studies referenced in the Cochrane Review.[7,8,25]

For the purposes of a full discussion, it is important to mention factors whose impact was not measured within the scope of our study. For some children, assisted-coughing maneuvers may have contributed to the results, even if the only practice being assessed in this clinical study was IET. Naturally, children with bronchiolitis cough spontaneously, which may contribute but is not sufficient alone, to reducing their symptoms, since coughing has little impact or "efficacy" on the distal airways.[28] Similarly, nasal irrigation does not

Table 6 Variation in scores

	Respiratory rate	Wheezing	Labored breathing
Before CP	29 infants with score of "2" (70.7%)	22 infants with score of "2" (53.7%)	20 infants with score of "2" (48.7%)
After CP	0 Infants	8 infants (19.5%)	9 infants (22%)

Abbreviation: CP, chest physiotherapy.

Table 7 Care pathway in the 7 days following inclusion ($n = 52$)

	Group A ($n = 31$)	Percentage	Group B ($n = 21$)	Percentage
Medical consultation	5	16.13	8	38.10
Related to bronchiolitis	1	3.23	5	23.81
Prescription renewal	3	9.68	1	4.76
Not related to bronchiolitis	3	9.68	3	14.29
Emergency room visit	1	3.23	3	14.29
Related to bronchiolitis	1	3.23	3	14.29
Not related to bronchiolitis	0	0	0	0
Hospitalization	0	0	1	4.76

change the intensity of wheezing. As other points out, there is a significant relationship between wheezing rates and the degree of bronchial obstruction.[29] Bearing in mind that the design of our study was intended to measure only short-term impacts, the data it generated do not allow us to reach conclusions about the potential long-term effects of the care received by study participants.

A discussion of the French National Health Authority's recommendations, issued in November 2019, mentioned a recent observational study, suggesting that some children may experience improvement in their condition after CP.[5] The data generated by our study are not sufficient to determine the characteristics of a such subpopulation.

Finally, from a care management perspective, while the French practice of prescribing outpatient CP with IET has not been based on any particular claims,[31] the rapid decrease in severe respiratory difficulties observed during our study helps explain some experts' position which was based on the observation of clear clinical improvement.[4] It also allows compliance with international recommendations on the need for discussion and study the clinical relevance of transient short-term relief for patients with bronchiolitis.[7]

It may also explain the position of the National Health Authority when, in 2019, it recommended that patients make use of the Bronchiolitis Network in France, comprised primarily of physiotherapists/massage therapists, which is part of the patient care pathway (►**Table 7**). Physiotherapists contribute to providing access to and continuity of unscheduled (emergency) care. Within the limits of their competence, they are able to identify any bronchial obstruction and to refer patients as necessary,[9] thus contributing to sharing information that may allow the physician to adjust diagnosis and treatment.

Conclusion

Our study suggests that CP can provide a positive effect on infants with moderate bronchiolitis in outpatient settings. This symptomatic action should be confirmed by improving comfort, sleep, and feeding for infants in a further quantitative study. Determining whether or not children are "responders" to guide decisions will also need futures researches too.

Conflicts of Interest
None declared.

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