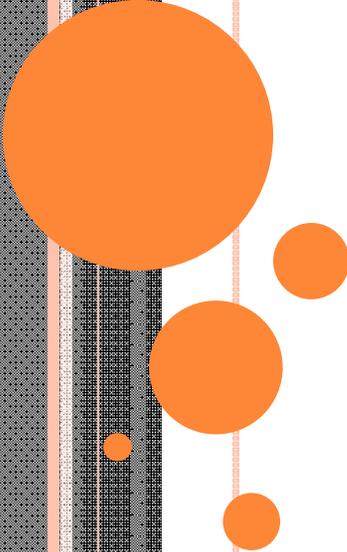


**EFFECTIVENESS OF CHEST PHYSIOTHERAPY  
IN INFANTS HOSPITALIZED WITH ACUTE  
BRONCHIOLITIS: *A MULTICENTER,  
RANDOMIZED, CONTROLLED TRIAL***

**PLOS HUB FOR CLINICAL TRIALS (SEP 2010)**

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○ **What evidence for chest physiotherapy in infants hospitalized for acute viral bronchiolitis?**



- Acute bronchiolitis is the leading cause of medical emergencies during winter in children younger than two years of age (1/3 infants < 1 yr-old; hospitalisation rate: 1% *or* 5 -17 /1,000 children <12 mo of age) → high utilisation of healthcare resources; overcrowding of hospitals during epidemics & significant morbidity for infants.

**Mortality rates:** 2 per 10,000 live births (Holman 2003: USA, 1996 - 1998).

- Chest physiotherapy is thought to assist infants in the clearance of secretions, improve oxygenation and to decrease ventilatory effort.



○ COCHRANE DATABASE 2008:

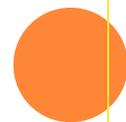
*Perrotta C, Ortiz Z, Roqué i Figuls M*

+**Three clinical trials** RCTs (2UK, 1Argentina)

+The study populations: hospitalised infants with a clinical diagnosis of acute bronchiolitis.

+All evaluated **vibration** and **percussion** techniques with children in **postural drainage positions** compared to **no intervention**.

+None of the other included trials observed any differences in: the **severity of the clinical score** at day five, during each of the five days of the trial, or until discharge; **length of hospital stay**; or **oxygen requirements** between paediatric patients receiving chest physiotherapy and control.



- In France, national guidelines 2001 recommend a specific type of physiotherapy: the increased exhalation technique (IET) + assisted cough (AC).
- Acceletation du flux expiratoire.mp4
- The objective: to evaluate the efficacy of chest physiotherapy (IET + AC) / infants hospitalized for an acute bronchiolitis.



- A multicenter, randomized, outcome assessor-blind and parent-blind trial.
- Populations: 496 infants (aged 15 days - 2 years) hospitalized for first-episode acute bronchiolitis in 7 French pediatric departments (Oct 2004 - Jan 2008).
- Patients were randomly allocated to receive from physiotherapists 3 times / day, either IET + AC (intervention group, n = 246) *or* nasal suction (NS, control group, n = 250). *Only physiotherapists were aware of the allocation group of the infant.*



Characteristic	NS (n=250)	IET + AC (n=246)
Age (mo), median [IQR]	2.0 [1.3–4.0]	2.1 [1.3–3.8]
Male gender, n (%)	141 (56.4)	134 (54.5)
Gestation (wk), mean ± SD	39.1 ± 1.65	39.1 ± 1.67
Environmental tobacco smoke <sup>a</sup> , n (%)	69 (29.0)	65 (26.9)
Personal eczema or history of atopy <sup>a,b</sup> , n (%)	100 (40.7)	97 (39.8)
Kindergarten <sup>a</sup> , n (%)	37 (15.0)	29 (12.0)
Bronchodilators before randomization <sup>a</sup> , n (%)	36 (14.4)	47 (19.1)
Corticosteroids before randomization <sup>a</sup> , n (%)	34 (13.6)	25 (10.2)
Feeding difficulties before randomization <sup>a</sup> , n (%)	222 (89.2)	207 (84.8)
Duration of respiratory symptoms at randomization in days <sup>a</sup> , median [IQR]	3.0 [2.0–4.0]	3.0 [2.0–4.0]
SpO <sub>2</sub> < 95% at randomization, n (%)	110 (44.2)	106 (44.2)
Atelectasia at randomization <sup>c</sup> , n (%)	31 (12.9)	18 (7.6)
Supplementary oxygen and intravenous feeding, n (%)		
No oxygen	141 (56.4)	135 (54.9)
Oxygen only	86 (34.4)	86 (34.9)
Oxygen and intravenous feeding	23 (9.2)	25 (10.2)
RSV +, n (%)	152 (76.4)	137 (73.3)
Temperature at randomization (°C), mean ± SD	37.2 ± 0.7	37.3 ± 0.6

<sup>a</sup>The data were obtained by parental reporting.

<sup>b</sup>History of atopy was defined as eczema or asthma in first-degree relatives.

<sup>c</sup>480 (96.7%) had X-ray at admission.

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**Table 1. Demographic characteristics of the infants on admission to the hospital.**



- The primary outcome was **time to recovery** = 8 hours without oxygen supplementation + minimal *or* no chest recession & ingesting more than two-thirds of daily food requirements.
- Secondary outcomes were **intensive care unit admissions**, **artificial ventilation**, antibiotic treatment, side effects during procedures, parental perception of comfort.



## RESULTS:

- Median time to recovery was 2.31 days, (95% confidence interval [CI] 1.97–2.73) for the control group and 2.02 days (95% CI 1.96–2.34) for the intervention group = no significant effect of physiotherapy (hazard ratio [HR] = 1.09, 95% CI 0.91–1.31,  $p = 0.33$ ).



Side Effect	NS (n=250)	IET + AC (n=246)	Relative Risk (95% CI)	p-Value <sup>a</sup>
Bradycardia with desaturation, n (%)	3 (1.2%)	3 (1.2%)	1.0 (0.2-5.0)	1.00
Bradycardia without desaturation, n (%)	2 (0.8%)	7 (2.8%)	3.6 (0.7-16.9)	0.10
Vomiting during procedure	1 (0.4%)	10 (4.1%)	10.2 (1.3-78.8)	0.005
Respiratory destabilization	3 (1.2%)	16 (6.5%)	5.4 (1.6-18.4)	0.002
Hypotonia	0 (0.0%)	2 (0.8%)	NA	0.24

<sup>a</sup>Fischer exact test.

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**Table 3: Side effects reported by physiotherapists during procedures.**



Parental Opinion	NS (n=187)	IET + AC (n=184)	Mean Difference [95% CI]	Relative Risk [95% CI]	p-Value
Evaluation de the comfort of your child during hospitalization, median (IQR)	7.8 [5.7-9.0]	7.5 [6.2-8.7]	-0.07 [-0.53 to 0.38]	—	0.40 <sup>d</sup>
Evaluation of the procedure arduous, median (IQR)	4.3 [2.0-6.3]	5.0 [3.0-7.1]	0.88 [0.33-1.44]	—	0.002 <sup>d</sup>
Influence of the physiotherapist visit on the comfort of your baby, n (%)			—	0.99 [0.90-1.08] <sup>b</sup>	0.89 <sup>e</sup>
Worsening	5 (2.7%)	12 (6.5%)	—	—	—
No influence	25 (13.4%)	19 (10.3%)	—	—	—
Improvement	157 (83.9%)	153 (83.2%)	—	—	—
Influence of the physiotherapist visit on the respiratory status of your baby, n (%)			—	0.99 [0.94-1.05] <sup>b</sup>	0.84 <sup>e</sup>
Worsening	4 (2.1%)	1 (0.5%)	—	—	—
No influence	8 (4.3%)	12 (6.6%)	—	—	—
Improvement	175 (93.6%)	170 (92.9%)	—	—	—

371 couples of parents (74.8%) completed the questionnaire. Percentages were calculated for the population of respondents (n = 371).

<sup>a</sup>Wilcoxon test.

<sup>b</sup>Relative risk was computed for improvement versus (no influence + worsening).

<sup>c</sup>Fischer Exact test.

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**Table 4: Parental opinions regarding the comfort of their child and the consequences of the procedure on this parameter and on the respiratory status.**



Secondary Outcome	NS (n = 250)	IET + AC (n = 246)	Relative Risk (95% CI)	p-Value <sup>a</sup>
PICU admission, n (%)	10 (4.1%)	7 (2.9%)	0.7 (0.3-1.8)	0.62
Ventilation, n (%)	2 (0.8%)	5 (2.0%)	2.5 (0.5-13.0)	0.29
Antibiotics	69 (28.5%)	67 (28.6%)	1.0 (0.7-1.3)	1.0
Relapse	53/182 (29.1%)	53/171 (31.0%)	1.1 (0.8-1.5)	0.73
New hospitalization	12/182 (6.6%)	14/171 (8.2%)	1.2 (0.6-2.6)	0.68

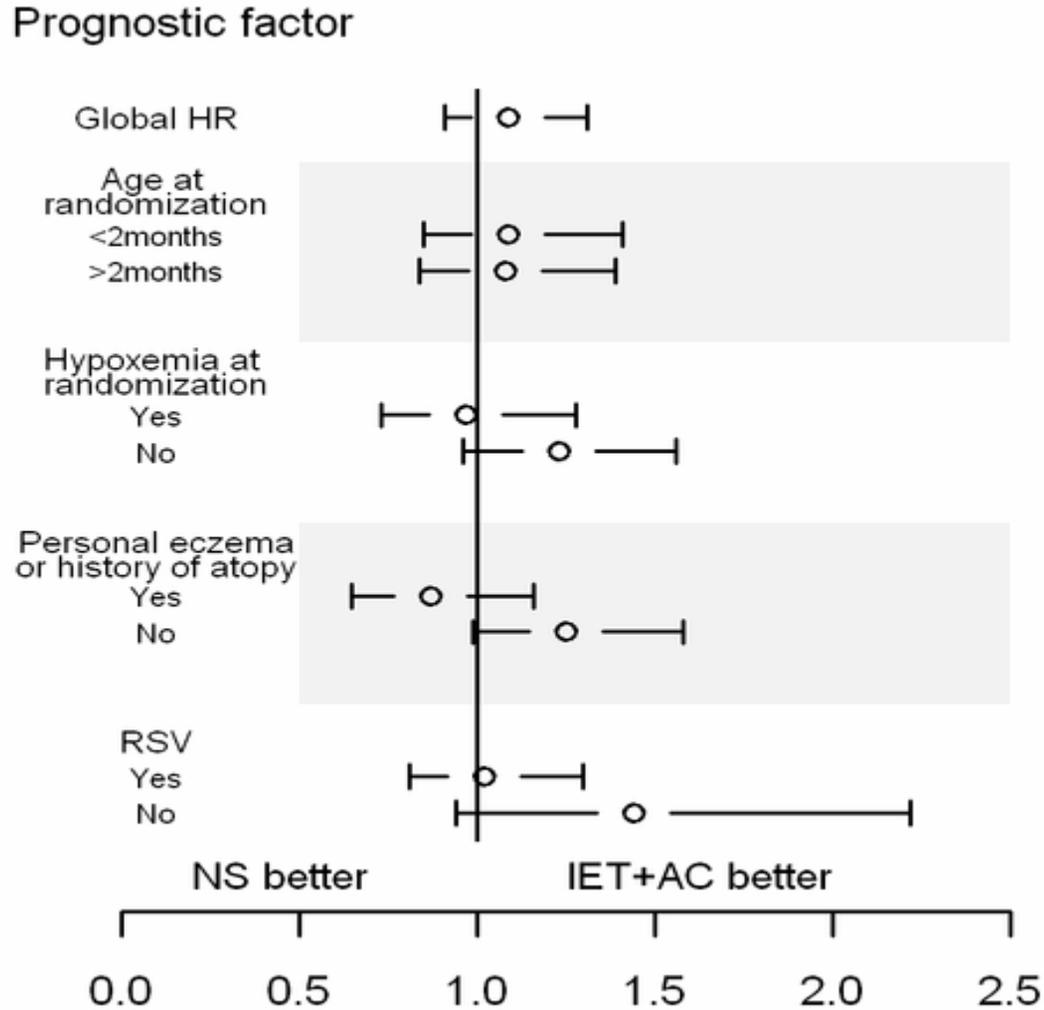
Data obtained from the parents by telephone interview 30 d after discharge. We obtained 353 responses (71.2%) and percentages were calculated for the population of respondents (n = 353).

<sup>a</sup>Fischer exact test for percentage comparison.

doi:10.1371/journal.pmed.1000345.t005

**Table 5: Secondary outcomes.**





**Figure 3: HRs and 95% CIs for healing in the group receiving IET + AC, as compared with the NS group, as a function of baseline prognostic factors.**



Prognostic Baseline Covariate	NS	IET + AC	HR (95% CI) of Recovery	p-Value <sup>a</sup>
	Median Time to Recovery, d (95% CI)			
Personal eczema or history of atopy <sup>b,c</sup>				0.06
Yes (n=197)	1.96 [1.36-2.73]	2.30 [1.73-3.07]	0.88 [0.66-1.17]	
No (n=293)	2.42 [2.04-2.85]	2.02 [1.92-2.33]	1.25 [0.99-1.58]	
RSV <sup>d</sup>				0.15
Positive (n=289)	2.34 [1.97-2.99]	2.33 [1.94-2.88]	1.01 [0.79-1.28]	
Negative (n=97)	2.33 [1.35-3.32]	1.92 [1.29-2.08]	1.43 [0.94-2.16]	
Hypoxemia at randomization				0.25
Yes (n=216)	2.73 [2.30-3.32]	2.47 [2.02-3.17]	0.99 [0.75-1.30]	
No (n=273)	1.90 [1.36-2.52]	1.96 [1.51-2.08]	1.23 [0.96-1.56]	

<sup>a</sup>p-Value refers to the statistics of Gail and Simon's quantitative interaction test (1df-chi-squared test).

<sup>b</sup>The data were obtained from the parents.

<sup>c</sup>History of atopy was defined as eczema or asthma in first-degree relatives.

<sup>d</sup>RSV was tested in only 386 infants.

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**Table 6. Search for treatment by covariate interactions on the main outcome measure, time to recovery.**



## CONCLUSIONS

- IET + AC had no significant effect on time to recovery in this group of hospitalized infants with bronchiolitis.
- Additional studies are required to explore the effect of chest physiotherapy on ambulatory populations and for infants without a history of atopy.

