Evidence Table

Clinical Area: High-frequency chest wall oscillation for patients with neuromuscular disorders.


Study Type: Randomized controlled trial.

Study Aim: To determine whether high-frequency chest wall oscillation (HFCWO) treatments are safe and well tolerated and can help facilitate mucociliary clearance and improve long-term respiratory health.

Outcomes:
- **Primary**: Incidence and duration of acute respiratory infections requiring antibiotics or hospitalizations, and occurrence of adverse events during the study period.

Design
- **Number of subjects**: N=28 randomized, N=23 included in the analysis (n=11 in the HFCWO group, and n=12 in the standard chest physiotherapy [CPT] group).
- **Description of study population**: The study recruited patients treated in a pediatric pulmonary clinic of a children’s university hospital in California. 12 had cerebral palsy (CP) and 16 a neuromuscular disease (NMD). Their mean age was around 13 years, and 65% were males.
- **Inclusion criteria**: 1. Diagnosis of NMD by genotype or muscle biopsy, or diagnosis of CP by a qualified medical specialist. 2. No acute respiratory distress.
- **Exclusion criteria**: Congestive heart failure or a contraindication to HFCWO use.
- **Intervention**: patients were randomised to receive either 1. Chest physiotherapy where caregivers were instructed to perform chest physiotherapy for 2 minutes in each of the 6 positions according to the hospital’s protocol. Or 2. High-frequency chest wall oscillation (HFCWO) where the patients were instructed to perform therapy at a frequency setting of 12 Hz and a machine pressure setting of 4. Caregivers were instructed to perform therapy for 12 minutes. Both therapy arms occurred under the observation of a respiratory therapist, and all participants were instructed to perform the therapy 3 times per day for the study period.
- **Source of outcome data**: Polysomnography to determine sleep efficiency, oxygenation, and any sleep-disordered breathing; chest radiography obtained at baseline and post-therapy follow-up to assess air trapping, linear markings, atelectasis and severity; BMI at baseline and post-therapy; and questionnaire to assess compliance with therapy.
- **Length of follow-up**: 5 months.

Validity
- **Blinding?** Patients were not blinded due to the nature of the intervention, and the authors did not indicate if assessment of outcomes were blinded.
- **Appropriate randomization procedures?** Not discussed.
- **Appropriate comparison intervention?** Yes.
- **Treatment/control groups comparable at baseline?** Yes.
- **Other than intervention, was care/follow-up similar in each group?** Yes.
- **Adequate compliance with intervention?** According to a questionnaire given to the caregivers, 56% of the patients included in the analysis had >70% adherence rate, 13 had a 30-70% adherence rate, and 35% had <30% adherence rate to therapy.
- **Sufficient statistical power?** The study was not powered to detect statistically significant differences between the study groups.
- **Intention to treat analysis?** No.
- **Completeness of follow-up**: 23 of the 28 (82%) randomized patients completed the trial.
Industry funding? Yes.

Conclusions regarding validity of methods:
The study was small, unblinded, had no power analysis or intention to treat analysis, had a short follow-up duration, and was funded by the manufacturer of the ABI system used.

Results

<table>
<thead>
<tr>
<th>Variables</th>
<th>Standard CPT</th>
<th>HFCWO</th>
<th>P value</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>No.</td>
<td>%</td>
<td>No.</td>
</tr>
<tr>
<td>All participants</td>
<td>n=12</td>
<td></td>
<td>n=11</td>
</tr>
<tr>
<td>Requiring hospitalization/IV antibiotics</td>
<td>4</td>
<td>33.3</td>
<td>0</td>
</tr>
<tr>
<td>Requiring oral antibiotics</td>
<td>7</td>
<td>58.3</td>
<td>3</td>
</tr>
<tr>
<td></td>
<td>n=5</td>
<td></td>
<td>n=4</td>
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<tr>
<td>CP group</td>
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<td>40.0</td>
<td>0</td>
</tr>
<tr>
<td>Requiring hospitalization/IV antibiotics</td>
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<td>80.0</td>
<td>1</td>
</tr>
<tr>
<td>NMD group</td>
<td>n=7</td>
<td></td>
<td>n=7</td>
</tr>
<tr>
<td>Requiring hospitalization/IV antibiotics</td>
<td>2</td>
<td>28.6</td>
<td>0</td>
</tr>
<tr>
<td>Requiring oral antibiotics</td>
<td>3</td>
<td>42.9</td>
<td>2</td>
</tr>
</tbody>
</table>

Adverse events:
No therapy adverse events occurred during the study.

Authors’ Conclusions
The authors concluded that the results of this pilot trial suggest that high-frequency chest wall oscillation is safe and tolerable in pediatric patients with cerebral palsy or neuromuscular disease.

Reviewer’s Conclusions
The trial does not provide sufficient evidence to determine that HFCWO is safe and/or is equivalent or superior to standard CPT for clearing airways and improving health outcomes in patients with neuromuscular disease.

The study had the advantage of comparing HFCWO to the standard CPT therapy in a RCT. However, it was too small, unblinded, included a heterogeneous group of patients, had a short follow-up duration, with no power analysis, no intention to treat analysis, and was financially supported by Hill-Rom Inc, the manufacturer of the airway clearing system used in the trial.