High-Frequency Assisted Airway Clearance

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Summary

High-frequency airway clearance assist devices generate either positive or negative transrespiratory pressure excursions to produce high-frequency, small-volume oscillations in the airways. Intrapulmonary percussive ventilation creates a positive transrespiratory pressure by injecting short, rapid inspiratory flow pulses into the airway opening and relies on chest wall elastic recoil for passive exhalation. High-frequency chest wall compression generates a negative transrespiratory pressure by compressing the chest externally to cause short, rapid expiratory flow pulses, and relies on chest wall elastic recoil to return the lungs to functional residual capacity. High-frequency chest wall oscillation uses a chest cuirass to generate biphasic changes in transrespiratory pressure. In any case (positive or negative pressure pulses or both), the general idea is get air behind secretions and move them toward the larger airways, where they can be coughed up and expectorated. These techniques have become ubiquitous enough to constitute a standard of care. Yet, despite over 20 years of research, clinical evidence of efficacy for them is still lacking. Indeed, there is insufficient evidence to support the use of any single airway clearance technique, let alone judge any one of them superior. Aside from patient preference and capability, cost-effectiveness studies based on existing clinical data are necessary to determine when a given technique is most practical. Key words: high frequency, airway clearance, secretion removal, intrapulmonary percussive ventilation, high-frequency chest wall compression, high-frequency chest wall oscillation. [Respir Care 2007;52(9):1224–1235. © 2007 Daedalus Enterprises]

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Introduction

High-frequency airway clearance techniques fall into 2 broad categories: unassisted and assisted. The definition of "assist" in this context is that the respiratory device (eg, ventilator) does work on the respiratory system, as indicated by an increase in transrespiratory pressure, associated with flow in the inspiratory direction, or a decrease in transrespiratory pressure, associated with flow in the expiratory direction.1 Unassisted methods that use devices such as the Flutter (Axcan Pharma, Mont-Saint-Hilaire, Quebec, Canada²), the Acapella (Smiths Medical, London, United Kingdom³), the Quake (Thayer Medical, Tucson, Arizona4), or the Lung Flute (Medical Acoustics, Buffalo, New York⁵) rely on the energy from passive exhalation to generate chest wall oscillations. Active devices, such as intrapulmonary percussive devices (eg, IPV-1S Universal Percussionator, Percussionaire, Sandpoint, Idaho⁶; PercussiveNeb, Vortran Medical Technology, Sacramento, California⁷; and IMP2, Breas Medical, Mölnlycke, Sweden⁸), the various vest devices (the Vest Airway Clearance System, Hill-Rom, St Paul, Minnesota9; SmartVest, Electromed, New Prague, Minnesota¹⁰; and inCourage, RespirTech, St Paul, Minnesota¹¹), and the Hayek oscillator (Breasy Medical Equipment, London, United Kingdom), create either a positive or negative transrespiratory pressure change (defined as a change in the pressure difference between pressure at the airway opening and the pressure on the body surface^{1,12}) to generate high-frequency, smallvolume oscillations in the airways.

Intrapulmonary percussive ventilation (IPV) creates positive changes in transrespiratory difference by injecting short, rapid inspiratory flow pulses into the airway opening and relies on chest wall elastic recoil for passive exhalation. Highfrequency chest wall compression (HFCWC) generates negative changes in transrespiratory pressure difference by compressing the chest externally (ie, body surface pressure goes positive relative to the pressure at the airway opening, which remains at atmospheric pressure) to cause short, rapid expiratory flow pulses, and relies on chest wall elastic recoil to return the lungs to functional residual capacity. High-frequency chest wall oscillation (HFCWO) uses a chest cuirass to generate biphasic changes in transrespiratory pressure difference. In any case (positive or negative pressure pulses or both), the general idea is to augment mucus movement toward the airway opening by a variety of mechanisms (to be explained below).

Note that there is no standardization of terminology in the literature, and the terms high-frequency chest wall oscillation, high-frequency chest wall compression, and high-frequency chest compression are often used interchangeably. The distinctions I have made in this paper are logical in that they are based on engineering principles and useful in that they dis-

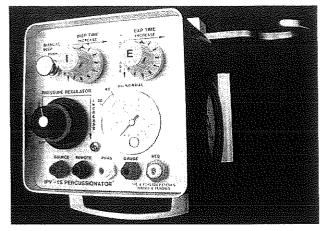


Fig. 1. Percussionaire Gold Edition IPV-1S Universal Percussionator. (Courtesy of Percussionaire, Sandpoint, Idaho).

tinguish among systems that differ in their availability and their implications for patient/caregiver education.

The goal of this paper is to describe the advantages and disadvantages of each of these approaches to assisted airway clearance and to review the evidence supporting their use. At present, the American Association for Respiratory Care clinical practice guidelines do not include these techniques.

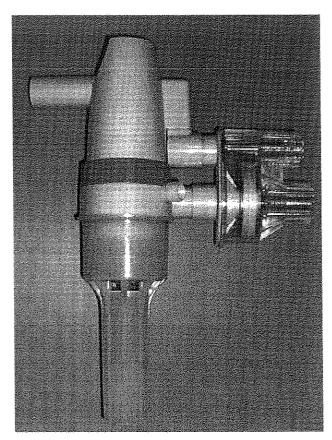


Fig. 2. Vortran PercussiveNeb. (Courtesy of Vortran Medical Technology, Sacramento, California.)

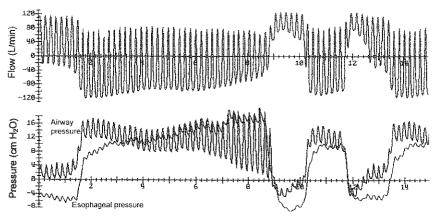


Fig. 3. Flow, airway pressure, and esophageal pressure waveforms while breathing with an intrapulmonary percussive ventilator. (From Reference 14)

Description of Technology

Intrapulmonary Percussive Ventilation

IPV was first described in 1985 as a new technique and device, invented by Dr Forrest Bird, for delivering aerosolized bronchodilators to patients with chronic obstructive pulmonary disease (COPD). 13 IPV was depicted as delivering "high flow mini-bursts of air along with bronchodilator to the lungs at a rate of 300-400 times per minute." The current version of Percussionaire's Percussionator (Fig. 1) operates at 1.7 Hz to 5 Hz and generates esophageal pressure and airflow oscillations as shown in Figure 2. Treatments last about 15-20 min. This device is designed to be used in conjunction with conventional mechanical ventilation, if desired, or as a stand-alone treatment device. It can be used with a mouthpiece or mask, and it can also deliver aerosolized medication. A device very similar to the Percussionator, the Breas IMP2, operates at about 1 Hz to over 6 Hz, and can also deliver aerosol. A disposable, single-patient-use IPV device (the PercussiveNeb [also known as P-Neb, and formerly marketed as the PercussiveTech HFI) is available from Vortran Medical (see Fig. 2). The PercussiveNeb operates at frequencies of 11-30 Hz, and can also deliver an aerosol. It cannot be used with a ventilator. All 3 devices produce roughly comparable pressure waveforms (Fig. 3)14 at a duty cycle of about 25-40% and amplitudes of about 10-30 H₂O (the IMP2 generates the lowest amplitude and the Percussionator generates the highest). 7,8,15 The exact value of pressure amplitude for either device is dependent on its pulsatile flow amplitude and the impedance of the respiratory system. These devices produce higher pressure amplitudes than unassisted high-frequency airway clearance devices (eg, Flutter and Acapella).16 All 3 devices are designed to deliver flow oscillations on top of a normal spontaneous breathing pattern.

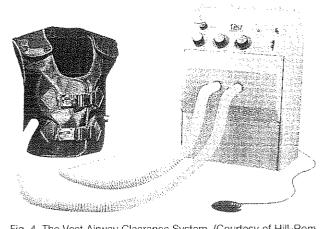


Fig. 4. The Vest Airway Clearance System. (Courtesy of Hill-Rom, St Paul, Minnesota.)

High-Frequency Chest Wall Compression

HFCWC is accomplished by encasing the chest in an inflatable vest. A high-output compressor rapidly inflates and deflates the vest. On inflation, pressure is exerted on the body surface (in the range of about 5–20 cm H₂O), which forces the chest wall to compress and generates a short burst of expiratory flow. Pressure pulses are superimposed on a small (about 12 cm H₂O) positive pressure baseline. On deflation, the chest wall recoils to its resting position, which causes flow in the inspiratory direction. The Vest Airway Clearance System (Fig. 4) operates at 2-25 Hz and generates esophageal pressure and airflow oscillations, as shown in Figure 5. The Vest manufacturer's literature states that HFCWC can generate volume changes from 17-57 mL and flows up to 1.6 L/s, which constitute "mini coughs" to mobilize secretions. A typical treatment may last 20-30 min, and consists of short time periods at different compression frequencies, separated by huff coughs.

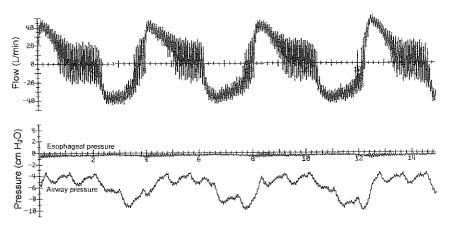


Fig. 5. Flow, airway pressure, and esophageal pressure waveforms while breathing with the Vest Airway Clearance System. (From Reference 14)

According to Milla et al, HFCWC with the Vest was originally delivered with a square pressure waveform, which was replaced with a sine waveform, but without published evidence of equality of effectiveness.¹⁷ Milla et al suggest that there are important differences between square, sine, and triangular waveforms in terms of patient volumes and flows, and that it may be best to "tune" each patient/vest combination for optimal secretion clearance.¹⁸

HFCWC causes a decrease in end-expiratory lung volume, but the consequences of that decrease are debatable. 19

High-Frequency Chest Wall Oscillation

HFCWO is achieved with a rigid chest cuirass connected to a compressor that can deliver both positive and negative pressures to the chest wall. This arrangement allows the most control over inspiratory and expiratory flow ratios, which, in theory (discussed below), may help to optimize mucus clearance. The Hayek oscillator (Fig. 6)20 operates at frequencies from about 1 Hz to 17 Hz and generates pressure and flow waveforms as shown in Figure 7. This device offers control of inspiratory-expiratory ratio (1:6 to 6:1) and inspiratory pressure (-70 cm H₂O to 70 cm H₂O). One of the preset modes is called "secretion mode,"21 which delivers a period of high-frequency/lowamplitude chest wall oscillation (T1) followed by a period of high-span oscillation at low frequency (T2). T1 lasts for 3 min with an inspiratory-expiratory ratio of 1:1, at 10 Hz, and with an inspiratory pressure of -12 cm H_2O and an expiratory pressure of 6 cm H₂O. T2 lasts for 3 minutes, has an inspiratory-expiratory ratio of 5:1, a frequency of 1 Hz, an inspiratory pressure of -24 cm H₂O, and an expiratory pressure of 12 cm H₂O.

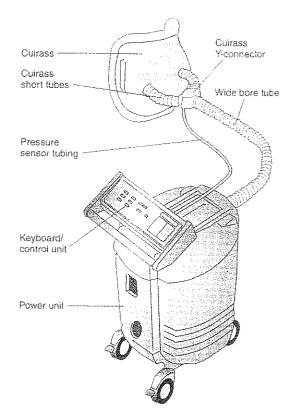


Fig. 6. The Hayek oscillator system. (From Reference 20, with permission.)

Mechanisms of Action

Numerous mechanisms have been proposed to explain the mucus transport effects of assisted airway clearance techniques.²² Perhaps the most intuitively obvious explanation is that mucus secretion is enhanced by air-liquid shear forces when expiratory flow is higher than inspiratory flow, just as with a normal cough. High-frequency

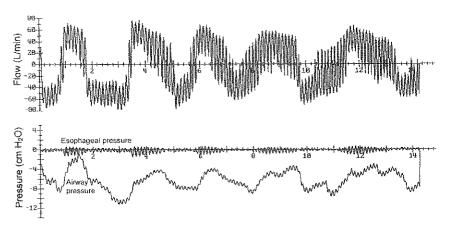


Fig. 7. Flow, airway pressure, and esophageal pressure waveforms while breathing with the Hayek oscillator. (From Reference 14)

devices simply stack many "mini coughs" into one spontaneous exhalation. Data from in vitro^{23,24} and in vivo²⁵ experiments supports this hypothesis. King et al²⁵ found that at 13 Hz, HFCWC enhanced tracheal mucus clearance rate over twice normal (in dogs) but high-frequency oscillation at the airway opening did not enhance the clearance rate. Nevertheless, clearance rate was greater when airway oscillation produced higher expiratory than inspiratory flows.

Based on theoretical considerations from previous studies, Scherer et al²⁶ developed a mathematical model to identify optimal settings for mucus transport:

$$OCI = f \times \frac{T_I}{T_E} \times \frac{\dot{V}_{E-max}}{\dot{V}_{I-max}} - f$$

where OCI = oscillatory clearance index, f = oscillatory frequency (Hz), T_1 = duration of outward inspiratory airway wall displacement, T_E = duration of inward expiratory airway wall displacement, \dot{V}_{E-max} = maximum expiratory flow, and \dot{V}_{I-max} = maximum inspiratory flow.

Frequency, T_{I} , and T_{E} are directly controllable by the operator on assisted airway clearance devices (except with the PercussiveNeb), whereas the maximum flows are indirectly controlled by the pressure settings. This model predicts that the higher the expiratory flow, the lower the inspiratory flow; the faster the inward displacement of the airway wall during expiration and the slower the outward displacement during inspiration, the higher the index and the faster the rate of mucus transport. With equal inspiratory and expiratory flows and wall displacements, OCI becomes zero. Despite its theoretical appeal, this model remains untested. Note, however, that pulsatile expiratory flow exceeds pulsatile inspiratory flow in all forms of high-frequency assisted airway clearance while the patient is exhaling (see Figs. 3, 5, and 7). This would suggest that the patient should be instructed to prolong exhalation as

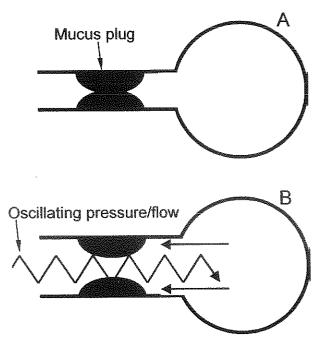


Fig. 8. Mechanism whereby an intrapulmonary percussive device creates small flow pulses and expands secretion-obstructed airways (A). Pressure accumulates behind the blocked areas and moves mucus toward the larger airways (B) to be coughed out. (Adapted from Vortran PercussiveNeb user's guide.)

long as possible to maximize the mucus clearance effect of different flows (a testable hypothesis for future studies).

Radial displacement of the airway wall may itself help disengage secretions and enhance the effect of air-liquid interaction on mucus movement.²⁷ This is a concept often mentioned by Forrest Bird in his explanations of IPV, and which is nicely illustrated in the PercussiveNeb user's guide (Fig. 8). The radial displacement idea may be supported by the study by Ravez et al,²⁸ who found that clearance of technetium-labeled microspheres was more effective after IPV treatment than was a control period in 7 of 10 patients

with chronic bronchitis. However, they concluded that overall, IPV had little effect on mucus transport and that improvement was due to the stimulation of a cough reflex.

High-frequency oscillations may have a mucolytic effect on bronchial secretions. King et al²⁹ found a frequency-dependent reduction in viscosity with oscillations from 3 Hz to 16 Hz. However, other researchers³⁰ found an increase in viscosity with oscillations from 1 Hz to 8 Hz. Tomkiewicz et al³¹ observed that viscosity decreased after 30 min of oscillation at a frequency of 22 Hz. Dasgupta et al³² found that combining HFCWC with recombinant human deoxyribonoclease (also known as rhDNase or dornase alfa) may provide greater benefits than treatment with one modality at a time.

There is unsupported speculation²² that ciliary beating may be enhanced during HFCWC. Vibration of the chest wall might stimulate the vagus nerve through reflex pathways in the airway walls or in the chest wall. Mechanical resonance (possibly in the range of 11–15 Hz) may increase the strength of the ciliary beat.

Evidence Supporting High-Frequency Assisted Airway Clearance

Intrapulmonary Percussive Ventilation

There have been a number of randomized controlled trials of IPV for airway clearance. In 1994, Natale et al³³ conducted a randomized crossover trial in a community-based cystic fibrosis (CF) referral center. Nine out-patients (age range 7–40 years, with moderate to excellent Shwachman scores) received albuterol via either IPV (Percussionator) or small-volume nebulizer (SVN) followed by conventional chest physical therapy (CPT) (chest percussion and postural drainage). There were no differences between the treatment groups in pulmonary function values nor volume or quality of sputum expectorated. Natale et al concluded that IPV was as effective as conventional CPT.³³

In another randomized crossover trail, Toussaint et al³⁴ compared a mucus clearance sequence that included forced expiratory technique and manual assisted cough, nebulized normal saline, and endotracheal suctioning to the same sequence plus IPV (Percussionator) in patients with muscular dystrophy. The weight of collected secretions was significantly higher with the treatment sequence that included IPV.

In 2005, Reardon et al³⁵ used a randomized controlled trial to compare the Percussionator to incentive spirometry in adolescents with neuromuscular disease. They found that antibiotic use was significantly less with IPV than with incentive spirometry. Furthermore, the IPV group had fewer days hospitalized and had zero episodes of pneu-

monia or bacterial bronchitis, compared to 3 events in the incentive spirometry group.

Also using the Percussionator, Vargas et al³⁶ showed that adding IPV to conventional CPT was associated with a significantly shorter hospital stay in patients with exacerbations of COPD. Exacerbation worsened in 6 of 17 patients in the CPT-only group, compared to 0 of 16 in the CPT plus IPV group.

More recently, 2 randomized controlled trials directly compared 1PV to CPT alone. In tracheostomized patients weaning from mechanical ventilation, Clini et al 37 found a better ratio of P_{aO_2} to fraction of inspired oxygen (P_{aO_2}/F_{IO_3}) , a higher peak expiratory pressure, and a lower incidence of pneumonia in the IPV group.

Antonaglia et al³⁸ also found a higher P_{aO_2}/F_{IO_2} with IPV in patients treated for COPD exacerbation. More importantly, they found significantly shorter duration of non-invasive ventilation and intensive care unit stay in the IPV group.

Varekojis et al³⁹ compared IPV (Percussionator) and HFCWC with CPT in 24 hospitalized patients with CF. Wet sputum weight was higher with IPV than HFCWC, but neither was different from CPT. These authors concluded that IPV and HFCWC are equivalent to CPT and might reasonably be substituted for CPT during CF exacerbations.

In a randomized controlled trial in 2002, my group compared IPV (Percussionator) to CPT for treatment of atelectasis. The study participants were 14 pediatric patients (age range 7 weeks to 14 years) who required mechanical ventilation. Based on a radiographic scoring system, the CPT group showed no change in atelectasis, compared to a significant improvement in the IPV group. The duration of treatment to the resolution of atelectasis was significantly less in the IPV group. There was no difference in static compliance. In 2006, Tsuruta et al IPV superimposed on conventional mechanical ventilation to treat obese patients who had acute respiratory failure due to compression atelectasis. As in other studies, IPV significantly increased P_{aO_2}/F_{IO_2} and compliance. Improvement in atelectasis was confirmed via computed tomography.

As good as the Percussionator seems to be for airway clearance and treatment of atelectasis, its performance as an aerosol delivery device is questionable. Reychler et al⁴² found that the amount of drug (amikacin) delivered to the lung with IPV was only 14% of the amount delivered with a standard SVN. The total amount of drug excreted in the urine was significantly lower with IPV than with the SVN. The IPV device fared slightly better in another study by the same group, ⁴³ in which the mass median aerodynamic diameter of aerosol particles produced with the Percussionator was much smaller than that from a standard SVN (0.2 μ m vs 1.9 μ m), and the IPV had a smaller fine-particle fraction (16.2% vs 67.5%). (These results may be

HIGH-FREQUENCY ASSISTED AIRWAY CLEARANCE

Table 1. Indications, Relative Contraindications, and Absolute Contraindications for High-Frequency Assisted Airway Clearance Devices*

Device	Indications	Relative Contraindications	Absolute Contraindications
Percussionaire IPV-1S Universal Percussionator (The user guide protocol's format is very similar to the AARC CPGs	Mobilizing pulmonary airways [sic], congested by secretion retention, mucosal and submucosal edema and bronchiolar spasm Creating a bilateral uniform alveolar ventilation for enhancing oxygen uptake and carbon dioxide elimination Mechanically mixing intrapulmonary gases through "diffuse intrapulmonary percussion" to enhance endobronchial diffusion of oxygen and the mobilization of peripheral CO ₂ Providing a major periodic "convective tidal flow" to wash out CO ₂ Potentially providing a mechanical "vesicular peristalsis" to augment "physiological vesicular peristalsis" within the pulmonary and bronchial circulations, as well as to provide for an augmenting "intrathoracic lymph	None stated in user guide	None stated in user guide
Vortran PercussiveNEB	pump." Mobilization of retained endobronchial secretions Resolution of diffuse patchy atelectasis Acute pulmonary edema Cystic fibrosis	History of pneumothorax Recent lobectomy/pneumonectomy Cardiovascular insufficiency Acute abdominal distention Poor patient cooperation Pulmonary air leak	Tension pneumothorax Actual or potential pulmonary hemorrhage Mechanical ventilation
Breas IMP2	Pulmonary recruitment Improvement of ventilation Optimizing gas exchange Prevention of pulmonary infections Aerosol therapy	None stated in user guide	None stated in user guide
Hill-Rom Vest Airway Clearance System	Documented need for airway clearance as defined by the AARC CPGs ⁶⁰ - Evidence of difficulty with secretion clearance - Presence of atelectasis caused by or suspected of being caused by mucus plugging - Diagnosis of disease such as cystic fibrosis, bronchiestasis, or cavitating lung disease Need for sputum sample for diagnostic evaluation	Intracranial pressure > 20 mm Hg or patients in whom increased intracranial pressure should be avoided Uncontrolled hypertension Hemodynamic instability Pulmonary edema associated with congestive heart failure Bronchopleural fistula Subcutaneous emphysema Recent esophageal surgery Active or recent hemoptysis Pulmonary embolism Uncontrolled airway at risk for aspiration Distended abdomen Bronchospasm Suspected pulmonary tuberculosis Transvenous pacemaker or	Head and/or neck injury that has no yet been stabilized Active hemorrhage with hemodynamic instability
		subcutaneous pacemaker	(Continue

Table 1. (Continued)

Device	Indications	Relative Contraindications	Absolute Contraindications	
Hill-Rom Vest Airway		Recent spinal surgery or acute spinal injury		
Clearance System		Rib fractures		
(Continued)		Surgical wound or healing tissue, recent skin grafts or flaps on the thorax		
		Burns, open wounds, and skin infections on the thorax		
		Lung contusion		
		Osteomyelitis of the ribs		
		Osteoporosis		
		Coagulopathy		
		Complaint of chest wall pain		

due to the design of the Percussionator, which uses entrained air to augment the flow from the SVN and hence may reduce particle size via evaporative loss.) Wholebody deposition of technetium-99m diethylenetriaminepenta-acetic acid in healthy subjects was significantly higher with IPV, but that was due to a higher extrapulmonary deposition. Intrapulmonary deposition was not different between the 2 devices, but it was much more variable with IPV than SVN. Reychler et al43 concluded that intrapulmonary deposition with the Percussionator was too unpredictable to recommend its use for drug delivery to the lung.

There have been no long-term studies of the PercussiveNeb. Marks et al reported use of the Percussive-Tech HF in patients with CF and concluded that it was safe and probably as effective as CPT.44 That same group compared daily use of the PercussiveTech HF with the Flutter (for CF) and found no differences in pulmonary function, days of hospital stay, or home intravenous antibiotic use.45

High-Frequency Chest Wall Compression

The device that would become the Vest Airway Clearance System was first described in 1983, when King et al²⁹ observed that the tracheal mucus transport rate in dogs could be increased as much as 340% at an HFCWC frequency of 13 Hz. Those results stimulated a number of supporting studies. Eight years later, Warwick and Hansen first reported the use of HFCWC in patients with CF.46 Those authors "tuned" the therapy by evaluating the relationship between frequency, volume, and flow, and arbitrarily selected the frequencies that provided the 3 highest flows and the 3 largest volumes. Each of those 6 frequencies was prescribed for 5 min, for a total treatment time of 30 min. These treatments resulted in positive effects on forced vital capacity and forced expiratory volume in the first second (FEV₁).

Overall, studies of the effects of HFCWC on sputum clearance or pulmonary function have been inconclusive. Some short-term crossover studies show improved outcomes (expectorated sputum weight), 47,48 and some showed no benefit (sputum weight, pulmonary function, saturation).49-51 Some authors believe that the preponderance of current opinion suggests that HFCWC increases mucolysis, mucus transport, and pulmonary function in patients with CF, while improving their quality of life. 19 A more conservative opinion is expressed in the current American College of Chest Physicians clinical practice guidelines:

> In patients with CF, devices designed to oscillate gas in the airway, either directly or by compressing the chest wall, can be considered as an alternative to chest physical therapy. Level of evidence: low. Benefit: conflicting. Grade of recommendation: L52

On the other hand, an argument can be made on the basis of non-airway-clearance considerations. Ohnsorg⁵³ reported in an abstract that he found a 49% reduction in the total direct expenditures for 23 CF patients after initiating Vest therapy. Whitman reported that 80% of respiratory therapists who used the Vest believed it saves time.51 One might also argue that patients prefer Vest therapy over manual CPT,54,55 although the opposite can also be argued.39 As for use in non-CF patients, a randomized controlled trial in patients with amyotrophic lateral sclerosis showed a decrease in symptoms of breathlessness, decreased fatigue, and a trend toward slowing the decline of forced vital capacity.56

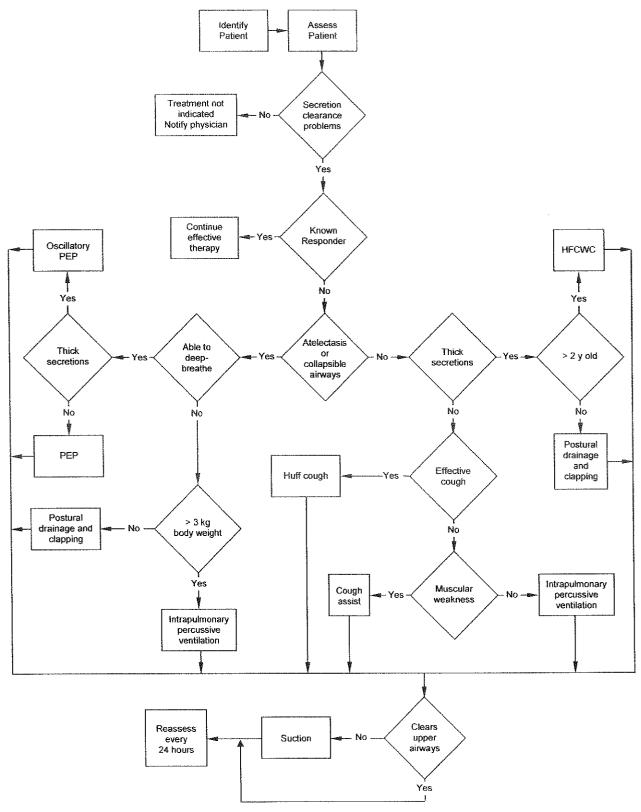


Fig. 9. Airway clearance algorithm. HFCWC = high-frequency chest wall compression. PEP = positive expiratory pressure therapy.

High-Frequency Chest Wall Oscillation

The Hayek oscillator got its start in an animal laboratory in the late 1980s.^{57–59} Early human studies showed that the device could sustain gas exchange in normals and in patients with COPD and with acute respiratory failure.⁶⁰ Apparently only one study has been published regarding airway clearance with the Hayek oscillator. This study of children with CF during infective exacerbation found that HFCWO was not effective for clearing bronchial secretions.²¹ The authors noted that the device is expensive and more children preferred active cycle of breathing techniques.

Indications and Contraindications for High-Frequency Assisted Airway Clearance

Table 1 shows the manufacturers' stated indications and contraindications.

Given the supporting data in the literature, it would seem that the Hill-Rom recommendations are the most clear and reasonable. I recommend that a committee sponsored by the American Association for Respiratory Care be convened to turn the information in the present paper into an official expert panel guideline. I would further recommend that the current postural drainage therapy guideline⁶¹ (which covers only postural drainage, percussion, and vibration) be replaced with a comprehensive guideline that puts into context the relative merits of both assisted and unassisted airway clearance techniques. An algorithm for this purpose is illustrated in Figure 9.

Summary

In 2001, Dean Hess made this statement in his landmark review of airway clearance procedures: "I conclude that there is insufficient evidence to support the use of *any* secretion clearance technique. . . . At best, the literature on this topic is disappointing." (emphasis mine)

Those opinions are echoed in the previously mentioned American College of Chest Physicians guidelines⁵² and a recent Cochrane review that stated:

This review demonstrated no advantage of conventional chest physical therapy techniques over other airway clearance techniques in terms of respiratory function. There was a trend for participants to prefer self-administered airway clearance techniques. Limitations of this review included a paucity of well-designed, adequately-powered, long-term trials.⁶³

To be fair, there have been 1 HFCWC and 8 IPV studies that showed benefit (but perhaps not strong evidence) since

Hess's review. Furthermore, the Cochrane review included only 3 high-frequency studies, and the primary outcome variable was pulmonary function status, not mucus clearance. One study in the review involved neither HFCWC nor HFCWO as described here, but treatment with a mechanical percussor. And another was just an abstract that compared CPT with "acoustic percussion." Thus, some of the data for HFCWC and much of that for IPV would argue for a more tolerant opinion. My own opinions about evidence-based indications for assisted airway clearance are that:

- IPV is probably better than CPT for atelectasis or secretion clearance.
- HFCWC is probably better than CPT for secretion clearance.
- HFCWO is probably effective, but not very practical for airway clearance, and it might be beneficial for noninvasive ventilation.

Nevertheless, when convincing experimental data are lacking or ambiguous, we are forced to rely on theory (first principles) and practical considerations. Given the time and resources already expended for so little result, it seems unlikely that acceptable *clinical* evidence for assisted (or unassisted) airway clearance techniques will be produced in the future. What we can and should expect, though, is a cost-effectiveness study. Many such examples (mostly for new drug therapy) can be found in the literature. 64,65 It would seem that there is no other way to distinguish among airway clearance techniques beyond patient preference. Use of self-administered airway clearance techniques may give patients a greater sense of independence. They offer advantages to those who lack the neuromuscular function to perform unassisted airway clearance techniques. 66

Beyond that, we need to select the technique that costs the least in terms of money, but especially in terms of time. There is a national shortage of respiratory therapists, which is probably going to get worse. The American Association for Respiratory Care 2005 Human Resources Survey⁶⁷ noted an increase of almost 3% in respiratory therapist vacancies between 2000 and 2005. According to the Ohio Hospital Association, both the turnover and vacancy rates for respiratory therapy were higher than those for nursing, radiology technology, and medical technology from 2004 through 2006. Turnover for respiratory therapists in Ohio for 2006 was estimated at 16.4%, and vacancy at 9.4%.68 The message is clear: we cannot wait for convincing evidence for all that we do, not just airway clearance. We must make use of economic and benchmarking studies to find ways to eliminate wasteful practices, and perhaps even to survive as a profession.

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Discussion

Branson: I'm looking at all the pediatric guys across from me. Every time somebody says something, I'm sitting here thinking, "No, it doesn't." Because my frame of reference is the trauma surgical ICU in patients with postoperative atelectasis, or on the ventilator. I think whenever you start to say something you ought to say, "for cystic fibrosis," or for whatever disease you're talking about, because I think it'll help in the discussion; when

the readers read it, they will know which patient population we're talking about.

Two comments. One, the way the IPV [intrapulmonary percussive ventilation] device works is by the Venturi principle. So, you have dry, anhydrous gas going in one side, entraining the aerosol. And of course, it's no surprise that the aerosol delivery is really poor in that case, because I'm sure it all ends up in the Venturi. So I think that makes perfect sense, what you showed.

And the other thing is that, at least in critically ill surgery patients, and post-op patients, we keep comparing all these new things to something that doesn't work, which is percussion with postural drainage. Maybe we ought to go back and start with, as you're suggesting, treatment just being normal airway suctioning, deep breathing, and coughing, as opposed to using percussion with postural drainage in that population of patients. I'm not suggesting that for CF.

Chatburn: Right. As far as the indications for atelectasis go, I mentioned 2 studies One was from our group with mechanically ventilated children. The other study involved obese patients. ^{1,2} Beyond that, I am not aware of any strong data.

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Hess: First a comment, then a question. I think we need to remember that lack of evidence does not necessarily mean lack of benefit. Which is the point that I was trying to make in that paper that you referred to. ^{1,2} From what I heard today, the evidence base is still not that great. That does not mean that some of these therapies are not beneficial, but I think we still lack good high-level studies for many of them.

With some of these devices, the manufacturers tout the ability to deliver aerosols, as you pointed out. And the question I have for you and maybe for the group is whether there is any evidence to support aerosolization of normal saline to enhance airway clearance? Is there evidence to support that?

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Rubin: Dean, I assume that's strictly a rhetorical question, that you've looked it up, and you know the answer.

Hess: Well, I know what my bias is.

Chatburn: I did not run into that. That wasn't the focus of my research. But I would just throw it out to the group.

MacIntyre: Rob, can I paraphrase a question I asked a little while ago?

These studies that use sputum volume as the end-point always make me a little nervous. Is there evidence that vibrating this cilia-mucus layer might actually stimulate further mucus production, and the reason you get more mucus is because you've irritated the airways and *made* more mucus? Is there evidence that suggests that might happen?

Chatburn: I did not see that kind of evidence when I looked at this literature.

Rubin: Although Duncan Rogers earlier presented the studies where they took airway secretory cells and collagen matrix, and by changing the shape by mechanical forces, were able to induce secretion. So, anything that gets these things jazzed up would probably induce secretion, although to my knowledge, that's hard to show in vivo.

MacIntyre: But again, it's a reason why I would argue that you really need outcome studies to show that these things make benefit. Because these intermediate end-points can fool you and may be misleading.

Rubin: I would agree fully. That was an absolutely brilliant talk, and actually it's been a great day, but the more we do this, the more we see that not only isn't there an evidence base to know if there's effectiveness or not, many of these interventions may be ineffective.

A tremendous amount of our time as therapists is spent doing this. You're chest pounders and neb jocks. And that's unfortunately all too true, and if there's a way to improve the therapy that we deliver as therapists, a way to provide the education we need to do, it's really, first and foremost, to eliminate all of the stuff that you're doing that you don't need to do. Another call for action, if you please.

Homnick: Rob, the single biggest problem I see with the airway oscillatory devices is their design. First, the PercussiveNeb—the forerunner to that was the PercussiveTech. formerly

marketed as the PercussiveTech HF is available from Vortran Medical.

Chatburn: Right. That's what's mentioned in the literature, right?

Homnick: Yes, and it does oscillate throughout both inspiration and expiration. Marks showed that in a study he did with flow tracings. But the one thing that neither device does, the IPV or the PercussiveNeb, PercussiveTech, is to provide that expiratory flow bias. And I think that's the critical issue.

Freitag showed years ago in anesthetized sheep that with a piston pump he was able to produce an expiratory flow bias that showed pretty significant cephalad flow of secretions,² and I don't think we have that with either of these devices. Now, could you design one like that that would run it at high enough frequency to be useful without breath stacking, I don't know that. But I just don't think we have a good design for oscillatory airway devices yet.

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Chatburn: I'd have to agree with that. Outside of the Hayek Oscillator, I don't know how you can get much better design than that. But as far as what you said about the expiratory flow bias, what you meant there, I think, was that you need to have a peak flow in the expiratory direction that's higher than the peak flow in the inspiratory direction. And I think that I tried to show in that one graphic we had 3-waveforms stacked up; you do get that effect for all of these devices.

In other words, during the expiratory phase of the spontaneous breath, oscillatory flow in the expiratory direction is the sum of the patient-generated flow and the device flow, whereas oscillatory flow in the inspiratory direction is the difference between the two. Thus oscillatory flow in the expiratory direction is higher, which should enhance mucus flow in that direction. But flow is not as controllable as maybe you would like it to be. So the effect is there only during the patient's spontaneous expiratory phase. If you oscillate on top of an exhalation, then that criterion is supported. On inspiration, it does not.

So, half the time you're sucking mucus in and half the time you're blowing it back out. That's why I suggested that perhaps there's a maneuver you can do here, where you have a short deep inspiration and a long expiration when you're using these devices, just for that reason.

Homnick: That's possible. Yes.

Fink: In the one article that you mentioned (Reychler et al¹) the aerosol particles with IPV was reported as $0.2~\mu m$ MMAD. The measurement of MMAD is typically done with a cascade impactor, and every cascade impactor I know requires some level of consistent flow. Consequently, use of a cascade impactor to measure aerosol delivery through an airway oscillator would appear to be a poor methods match, making it impossible to measure a reasonably accurate particle size distribution.

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Chatburn: I agree. In my experience, there is as much art as science in using a cascade impactor even under ideal conditions.

Pierson:* Are there types of patients or clinical circumstances in which these high-frequency airway assistors *shouldn't* be used? I'm thinking, per-

haps, of patients with neuromuscular disease who might have a lot of secretions during an infection episode, but be unable to expectorate.

Chatburn: That's a good question. I don't know. It's the same issue with a mucolytic in a patient like that. If you mobilize secretions, the patient must be able to cough them out. And perhaps these techniques don't actually bring them out; they bring them to the larger airways and then depend on the patient's cough ability to bring them up.

Fink: Whether at home or in the acute care setting, there are available mechanisms to assist clearance of the central airways. The adage of "don't mobilize secretions if you can't clear the airway" is best seen as a reminder to the clinician that such mechanisms are available to the patient. While mechanical aspiration and devices like the in-exsufflator can effectively clear the central airways, we have no way mechanically to aspirate secretions past the 4th generation of the airway, with the exception of bronchoscopy, which is not a cost effective option for routine care.

Giordano: Were any of the studies focused on the impact of the intervention with regard to compliance? The point has been raised that we're using these interventions to treat individuals with chronic diseases; compliance is always an issue, and even though we don't see the clinical metrics, are we getting better compliance with one clinical intervention, as opposed to another? That's almost of equal importance to the clinical outcomes' effectiveness, because one can have the most effective thing in the world, but if nobody comes to the dance, it won't matter!

Chatburn: That's true. Some of the studies did mention adherence, only in terms of patient preference. None of them that I saw measured it.

Hess: Rob, could you comment on the cost of these devices? You did make a point that they are less costly, but is not the initial cost of some of these quite high? So how do you get a lower cost with something that costs a lot of money to buy in the first place?

Chatburn: Hence my suggestion for a cost-effectiveness study. I don't have the data, but that is the question we need to ask. And as Bruce [Rubin] pointed out earlier, particularly with our national labor shortage, I think we need to be looking at working smarter and decreasing the work load associated with these therapies. And that is something that is a very serious problem, I think.

Rogers: I noticed that one of the contraindications to some of the machines was pulmonary hemorrhage. In what sort of patients, and under what sort of conditions, would you get pulmonary hemorrhage, and how would you treat it, or go about avoiding it?

Chatburn: Well, I don't think the lists were suggesting that you would get a pulmonary hemorrhage from therapy; perhaps it would just exacerbate it. And if you were already bleeding, that oscillating and shaking up the airways would possibly cause more bleeding. But I don't think anybody here suggested that it would cause it initially. Again, there's nothing in the literature that specifically addresses the issue; it's just my own common sense interpretation.

Rubin: This is a North American sort of thing, Duncan. There are 2 bits. First, if you're bleeding and you've got a little tiny clot and knock it loose, could you make it worse? But even if not, since a lot of patients who have bronchial bleeds with bronchiectasis have little bleeds and then a big one, and in between you *happen* to have used one of these devices, whether or not it caused anything, there could be the perception you caused it.

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