# **Chest Physiotherapy and Airway Clearance Devices AHM**



# **Clinical Indications**

- Home chest physiotherapy by a respiratory therapist is considered medically necessary for **1 or more** of the following
  - Initial prescription of chest physiotherapy to stabilize the member and to train family members or caregivers to administer chest physiotherapy
  - o When the member's pulmonary condition is unstable
    - Chest physiotherapy by a respiratory therapist is not considered medically necessary for persons whose pulmonary condition is stable, as chest physiotherapy can be competently administered at home by a family member or caregiver.
- The following airway clearance devices medically necessary durable medical equipment (DME) to assist in mobilizing respiratory tract secretions for members with the conditions that are indicated below. Select from 1 or more of the following
  - Airway oscillating devices (e.g., Flutter and Acapella) are considered medically necessary for cystic fibrosis, chronic bronchitis, bronchiectasis, immotile cilia syndrome and asthma
  - Mechanical percussors (e.g., Fluid Flo and Frequencer) are considered medically necessary for cystic fibrosis, chronic bronchitis, bronchiectasis, immotile cilia syndrome, and asthma
  - Positive expiratory pressure (PEP) mask is considered medically necessary for cystic fibrosis, chronic bronchitis, immotile cilia syndrome asthma, and chronic obstructive pulmonary disease
- High-frequency chest compression systems (e.g., the Frequencer, the SmartVest, the MedPulse Respiratory Vest System, the Vest Airway Clearance System, the ABI Vest, Respin11 Bronchial Clearance System, and the InCourage Vest/System) are considered medically necessary in lieu of chest physiotherapy for 1 or more of the following indications, where there is a documented failure of standard treatments to adequately mobilize retained secretions.
  - Bronchiectasis, confirmed by CT scan, characterized by daily productive cough for at least 6 continuous months or by frequent (more than 2 times per year) exacerbations requiring antibiotic therapy
  - o Cystic fibrosis or immotile cilia syndrome
  - The patient has **1 or more** of the following neuromuscular disease diagnoses
    - Acid maltase deficiency
    - Anterior horn cell diseases; including amyotrophic lateral sclerosis
    - Hereditary muscular dystrophy
    - Multiple sclerosis
    - Myotonic disorders
    - Other myopathies

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- Paralysis of the diaphragm
- Post-polio
- Quadriplegia
- Lung transplant recipients, within the first 6 months post-operatively, who are unable to tolerate standard chest physiotherapy.
- Mechanical in-exsufflation devices medically are considered necessary DME for patients with a
  neuromuscular disease including 1 or more of the following that is causing asignificant impairment of chest
  wall and/or diaphragmatic movement and for whom standard treatments (e.g., chest percussion and postural
  drainage, etc.) have not been successful in adequately mobilizing retained secretions
  - o amyotrophic lateral sclerosis
  - o high spinal cord injury with quadriplegia
- Current role remains uncertain. Based on review of existing evidence, there are currently no clinical indications for this technology. See Inappropriate Uses for more detailed analysis of the evidence base. -Highfrequency chest compression systems are considered experimental and investigational for the following indications (not an all inclusive list)
  - o alpha 1-antitrypsin deficiency
  - o cerebral palsy
  - o **coma**
  - o kyphosis
  - o leukodystrophy
  - o scoliosis
  - o stiff-person (stiff-man) syndrome
- Current role remains uncertain. Based on review of existing evidence, there are currently no clinical indications for this technology. See Inappropriate Uses for more detailed analysis of the evidence base. Intrapulmonary percussive ventilators (IPV) are considered experimental and investigational as there is insufficient evidence supporting their effectiveness

# **Evidence Summary**

- Background
- Cystic fibrosis (CF), chronic bronchitis, bronchiectasis, immotile cilia syndrome, asthma, and some acute respiratory tract infections can lead to abnormal airway clearance or increase sputum production. Airway secretions are cleared by mucociliary clearance (MCC), in addition to other mechanisms such as cough, peristalsis, two-phase gas-liquid flow and alveolar clearance. The underlying pathology of abnormal airway clearance differs from one illness to another. Chest physiotherapy (CPT) is a treatment program that attempts to compensate for abnormal airway clearance. By removing mucopurulent secretions, it decreases airway obstruction and its consequences, such as atelectasis and hyperinflation; furthermore, physiotherapy can decrease the rate of proteolytic tissue damage by removing infected secretions. Methods to improve removal of tenacious lung secretions in patients with CF contribute to slowing the decline in respiratory function.

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- The standard dependent method of pulmonary care remains clapping, vibration and compression, together with postural drainage and assisted coughing. Most practitioners prescribe 20 to 30-minute CPT sessions one to three times a day, depending on the severity of disease and the presence of intercurrent infection.
- Respiratory therapists can teach family patients or other informal caregivers to competently administer manual chest physiotherapy (CPT) to children and others who are incapable of doing it for themselves. The National Heart Lung and Blood Institute (1995) of the National Institutes of Health states: "Chest therapy consists of bronchial, or postural, drainage, which is done by placing the patient in a position that allows drainage of the mucus from the lungs. At the same time, the chest or back is clapped (percussed) and vibrated to dislodge the mucus and help it move out of the airways. This process is repeated over different parts of the chest and back to loosen the mucus in different areas of each lung. This procedure has to be done for children by family patients but older patients can learn to do it by themselves. Mechanical aids that help chest physical therapy are available commercially."
- Different types of airway clearance devices have been developed for independent use, which require little or no assistance by others. When a competent care giver is not available to administer CPT manually, specific alternative methods may be utilized. Many of these techniques have been developed and studied using CF patients.
- De Boeck and colleagues (2008) noted that airway clearance techniques are an important part of the
  respiratory management in children with CF, bronchiectasis and neuromuscular disease. They are also,
  however, frequently prescribed in previously healthy children with an acute respiratory problem with the aim to
  speed up recovery. These investigators reviewed the evidence behind this use of airway clearance
  techniques in children without underlying disease. They stated that few studies have been performed; many
  different techniques are available and the therapies used are often poorly specified. It is necessary to name
  the specific airway clearance technique used in treatment rather than to just state "chest physiotherapy," a
  term that is often confused with chest clapping or vibration plus postural drainage. There is little evidence that
  airway clearance techniques play a role in the management of children with an acute respiratory problem.
  Physicians routinely prescribing airway clearance techniques in previously healthy children should question
  their practice.
- A high-frequency chest wall compression device (The Vest Airway Clearance System, formerly known as the ThAIRapy Vest, ABI Vest) (Advanced Respiratory, St. Paul, MN) is an inflatable vest connected to a compressor that provides external high-frequency chest wall oscillation. The vest is connected via tubing to an air pulse delivery system. The patient then uses a foot pedal to apply pressure pulses that cause the vest to inflate and deflate against the thorax creating an oscillatory or vibratory motion.
- High-frequency chest compression devices have been shown to increase sputum production in CF patients. CF is caused by abnormal chloride ion transport on the apical surface of epithelial cells in exocrine gland tissues. The abnormally composition of secretions from affected epithelial surfaces results in increased viscosity. It has been theorized that high-frequency chest compression devices are particularly effective in clearing the abnormal secretions of CF because vibratory shear forces facilitate expectoration by reducing the viscosity of these secretions, much in the same way that shaking jello causes it to become fluid. However, high frequency chest compression vests have not been proven to be more effective than manual chest

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physiotherapy. It can be used in place of manual chest physiotherapy for patients with CF where manual chest physiotherapy is unavailable.

- High-frequency chest wall compression devices have been promoted for use in conditions other than cystic fibrosis, including non-CF bronchiectasis. However, there are no adequate published controlled clinical studies of high-frequency chest compression devices for conditions other than cystic fibrosis. Given the unique pathophysiology of cystic fibrosis resulting in the abnormal composition of CF secretions, evidence of the effectiveness of high-frequency chest wall compression devices in CF cannot be extrapolated to other pulmonary conditions. The Vest was cleared by the FDA for a wide variety of pulmonary conditions based on a 510(k) premarket notification; thus the manufacturer was not required to submit the type of evidence of effectiveness that would be required to support a pre-market approval (PMA) application.
- In addition, there are no adequate studies comparing high frequency chest compression to other, relatively simple and substantially less expensive devices (e.g., Flutter, Acapella) that apply high-frequency oscillation to the airway.
- The American College of Chest Physicians' evidence-based clinical practice guidelines on non-pharmacologic airway clearance therapies (McCool and Rosen, 2006) recommend oscillatory devices (e.g., Flutter, IPV, and HFCWO) to be considered as an alternative to chest physiotherapy only in CF patients.
- The Vest is only available for purchase (it cannot be rented); the air pulse delivery system (an air-pulse generator) and flexible hoses are available for rental or purchase.
- There is controversy surrounding the use of high-frequency chest physiotherapy devices for indications other than CF.
- Yuan and colleagues (2010) stated that airway secretions and infections are common in cerebral palsy and neuromuscular diseases. Chest physiotherapy is standard therapy but effort is substantial. High-frequency chest wall oscillation is used in CF but tolerability and safety data in cerebral palsy and neuromuscular disease are limited. These researchers performed a prospective, randomized, controlled trial of HFCWO and standard CPT in patients with neuromuscular disease or cerebral palsy (CP). Outcome measures included respiratory-related hospitalizations, antibiotic therapy, chest radiographs, and polysomnography. Care-givers were questioned regarding therapy adherence. A total of 28 participants enrolled, 23 completed (12 CPT, mean study period 5 months). No adverse outcomes were reported. Adherence to prescribed regimen was higher with HFCWO (p = 0.036). These findings suggest safety, tolerability, and better compliance with HFCWO. Improvement in airway clearance may help prevent hospitalizations. The authors noted that larger controlled trials are needed to confirm these results.
- Drosman and Jones (2005) noted that, in the pediatric population, HFCWO is most widely used in children
  with cystic fibrosis, but that children with developmental disorders involving neuromuscular dysfunction also
  have impaired airway clearance with or without ventilatory dependence. The authors stated that "[I]arge, longterm studies are needed examining HFCC in the patients with developmental disorders."
- In an "exploratory" randomized controlled trial, Lange et al (2006) assessed changes in respiratory function in patients with amyotrophic lateral sclerosis (ALS) after using high-frequency chest wall oscillation (HFCWO). This was a 12-week study of HFCWO in patients with probable or definite ALS, an Amyotrophic Lateral Sclerosis Functional Rating Scale respiratory subscale score less than or equal to 11 and greater than or

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equal to 5, and forced vital capacity (FVC) greater than or equal to 40 % predicted. A total of 46 patients were enrolled (58.0 +/- 9.8 years; 21 men, 25 women); 22 used HFCWO and 24 were untreated. Only thirty-five completed the trial: 19 used HFCWO and 16 untreated. Results were reported per-protocol, rather than by intention-to-treat. HFCWO users had less breathlessness (p = 0.021) and coughed more at night (p = 0.048) at 12 weeks compared to baseline. At 12 weeks, HFCWO users reported a decline in breathlessness (p = 0.048); non-users reported more noise when breathing (p = 0.027). There were no significant differences in FVC change, peak expiratory flow, capnography, oxygen saturation, fatigue, functional quality of life, or transitional dyspnea index. When patients with FVC between 40 and 70 % predicted were analyzed, FVC showed a significant mean decrease in untreated patients but not in HFCWO patients; HFCWO patients had significantly less increased fatigue and breathlessness. Satisfaction with HFCWO was 79 %. The authors concluded that HFCWO was well-tolerated, considered helpful by a majority of patients, and decreased symptoms of breathlessness. In patients with impaired breathing, HFCWO decreased fatigue and showed a trend toward slowing the decline of forced vital capacity. The investigators explained that the study was exploratory in nature, and was not sufficiently powered to detect significant differences in clinical outcomes such as pulmonary complications, hospitalizations or mortality.

- On the other hand, Chaisson et al (2006) did not find HFCWO to be of significant help to patients with ALS. These investigators evaluated the effectiveness of HFCWO administered through the Vest Airway Clearance System when added to standard care in preventing pulmonary complications and prolonging the time to death in patients with ALS. A total of 9 patients with a diagnosis of ALS and concurrently receiving non-invasive ventilatory support with bi-level positive airway pressure (BiPAP) were recruited from an outpatient clinic. Four patients were randomized to receive standard care and 5 patients to receive standard care plus the addition of HFCWO administered twice-daily for 15 min duration. Longitudinal assessments of oxyhemoglobin saturation, forced FVC), and adverse events were obtained until time of death. Pulmonary complications of atelectasis, pneumonia, hospitalization for a respiratory-related abnormality, and tracheostomy with mechanical ventilation were monitored throughout the study duration. No differences were observed between treatment groups in relation to the rate of decline in FVC. The addition of HFCWO airway clearance failed to improve time to death compared to standard treatment alone (340 days +/- 247 versus 470 days +/- 241; p = 0.26). The random allocation of HFCWO airway clearance to patients with ALS concomitantly receiving BiPAP failed to attain any significant clinical benefits in relation to either loss of lung function or mortality. This study does not exclude the potential benefit of HFCWO in select patients with ALS who have coexistent pulmonary diseases, pre-existent mucus-related pulmonary complications, or less severe levels of respiratory muscle weakness.
- Although clinical evidence is limited, high frequency chest wall oscillation devices have been used for lung transplant recipients who are unable to tolerate standard chest physiotherapy in the postoperative period.
- The purpose of percussion is to apply kinetic energy to the chest wall and lung at regular intervals. Percussion
  is also referred to as cupping, clapping, and tapotement. It can be accomplished by rhythmically striking the
  thorax with a cupped hand or a mechanical device applied directly over the lung segment(s) being drained.
  According to the guidelines developed by American Association for Respiratory Care (AARC) on postural
  drainage therapy, no convincing evidence demonstrates the superiority of one method over the other;

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however, use of a mechanical percussor can benefit the patient by allowing for independence and greater compliance.

- The Flutter (Scandipharm, Birmingham, AL) is a handheld pipe-like device with a plastic mouthpiece on one end that the patient exhales into. On the other end of the pipe, a stainless steel ball rests inside a plastic circular cone. When the patient exhales into the device, the ball rolls and moves up and down, creating an opening and closing cycle over a conical canal. The cycle repeats itself many times throughout each exhalation intending to produce oscillations of endobronchial pressure and expiratory airflow that will vibrate the airway walls and loosen mucus so that it can be easily expectorated by the patient. The Flutter device has 510(k) status with the FDA. Although the Flutter device has not been shown to significantly change respiratory assessment parameters or pulmonary function, some patients may prefer this method over other therapies.
- A similar oscillatory positive airway pressure device, the Acapella (Smiths Medical, Watford, UK), uses a counterweighted plug and magnet to create air flow oscillation. Volsko, et al. (2003) noted that the Acapella and Flutter have similar performance characteristics. The author noted that the Acapella's performance is not gravity-dependent (i.e., dependent on device orientation) and may be easier to use for some patients.
- The PEP mask/mouthpiece contains a valve that increases resistance to expiratory airflow. The patient
  breathes in and out 5 to 20 times through the flow resistor, creating positive pressure in the airways during
  exhalation. The pressure generated can be monitored and adjusted with a manometer. Either low pressures
  or high pressures are prescribed. The PEP mask/mouthpiece achieves the same goal as autogenic drainage
  (a special breathing technique aimed at avoiding airway compression by reducing positive expiratory
  transthoracic pressure) by expiring against an external airflow obstruction.
- Most studies on the effectiveness of PEP have been conducted in Europe and they reported short-term equivalency of PEP to other methods of airway clearance. A published review of these studies found that PEP had similar effects on sputum clearance when compared with other methods (postural drainage forced exhalatory technique). The strongest evidence of the effectiveness of PEP comes from a 1-year randomized controlled clinical trial of PEP vs. conventional physiotherapy in 40 children with CF. The patients treated with PEP showed improvements in pulmonary function, whereas pulmonary function actually declined in patients treated with conventional physiotherapy. The differences between treatment groups were statistically significant for changes in FVC and FEV1.
- There are numerous PEP Mask/PEP Valves on the market. Examples include: Resistex PEP Mask (Mercury Medical, Clearwater, FL), TheraPep Valve (DHD Healthcare, Inc., Canastota, NY), Acapella (DHD Healthcare, Inc., Wampsville, NY) and PARI PEP Mask (PARI Respiratory Equipment, Inc., Midlothian, VA).
- Intrapulmonary Percussive Ventilator (IPV) (Percussionaire Corporation, Sandpoint, ID) is an aerosol machine
  that delivers a series of pressurized gas minibursts at rates of 100-225 cycles per minute to the respiratory
  tract. Aerosolized medications can be delivered under pressure and with oscillations that vibrate the chest. In
  contrast to PEP and flutter, IPV allows continuous monitored positive pressure application and percussion
  throughout the respiratory cycle. The patient controls variables such as inspiratory time, peak pressure and
  delivery rates. The Percussionaire has 510(k) status with the FDA.
- There is a scarcity of scientific data to support the effectiveness of IPV. A small study (n = 16) by Homnick, et al. (1995) found IPV as effective as standard aerosol and chest physiotherapy in preserving lung function. A

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study by Newhouse, et al. (1998) concluded that larger and longer studies of IPV compared to standard chest physiotherapy are needed to evaluate its value for independent administration of chest physiotherapy. Studies do not demonstrate any advantage of IPV over that achieved with good pulmonary care in the hospital environment and there are no studies in the home setting.

- Reychler et al (2006) stated that IPV, frequently coupled with a nebulizer, is increasingly used as a physiotherapy technique. However, its physiological and clinical values have been poorly studied. These researchers compared lung deposition of amikacin by the nebulizer of the IPV device and that of standard jet nebulization (SJN). Amikacin was nebulized with both devices in a group of 5 healthy subjects during spontaneous breathing. The deposition of amikacin was measured by urinary monitoring. Drug output of both devices was measured. Respiratory frequency (RF) was significantly lower when comparing the IPV device with SJN (8.2 +/- 1.6 breaths/min versus 12.6 +/- 2.5 breaths/min, p < 0.05). The total daily amount of amikacin excreted in the urine was significantly lower with IPV than with SJN (0.8 % initial dose versus 5.6 % initial dose, p < 0.001). Elimination half-life was identical with both devices. Drug output was lower with IPV than with SJN. The amount of amikacin delivered to the lung is 6-fold lower with IPV than with SJN, although a lower RF was adopted by the subjects with the IPV. The authors concluded that the IPV seems unfavorable for the nebulization of antibiotics.</p>
- Brückner (2008) stated that assisted coughing and mechanical cough aids compensate for the weak cough flow in patients with neuromuscular diseases (NMD). In cases with preserved respiratory muscles, breathing techniques and special devices (e.g., Flutter or Acapella) can be used for secretion mobilization during infections of the airways. These physiotherapeutic approaches were summarized as oscillating physiotherapy. Their mechanisms are dependent on separation of the mucus from the bronchial wall by vibration, thus facilitating mucus transport from the peripheral to the central airways. In mucoviscidosis and chronic obstructive pulmonary disease their application is established, but there is a paucity of data regarding the commitment in patients with NMD. The effective adoption of simple oscillating therapeutic interventions demands usually a sufficient force of the respiratory muscles -- exceptions are the application of the Percussionaire (i.e., IPV) or high frequency chest wall oscillation (HFCWO). In daily practice there is evidence that patients with weak respiratory muscles are over-strained with the use of these approaches, or get exhausted. A general recommendation for the adoption of simple oscillating physiotherapeutic interventions cannot be made in patients with NMD. Perhaps in the future devices such as IPV or HFCWO will prove to be more effective in patients with NMD.
- Mechanical insufflation-exsufflation (CoughAssist, J.H. Emerson Co., Cambridge, MA) (also known as In-Exsufflator, Cofflator, cough machine) is designed to inflate the lung with positive pressure and assist cough with negative pressure; it is advocated for use in patients with neuromuscular diseases. The published literature on the effectiveness of mechanical insufflation-exsufflation consists of review articles, case reports, retrospective analyses, and small, uncontrolled case series. In addition, published research on mechanical insufflation-exsufflation-exsufflation has come from a single investigator, raising questions about the generalization of findings. A Consensus Panel Report by the American College of Chest Physicians (Irwin, et al., 1998) stated that "[t]he inability of patients with respiratory muscle weakness to achieve high lung volumes is likely to contribute to cough ineffectiveness. Increasing the inhaled volume prior to cough by air-stacking positive

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pressure breaths or by glossopharyngeal breathing increases cough expiratory flows by 80% in these patients. Cough efficiency may be further enhanced by the application of negative pressure to the airway for a period of 1 to 3 s. Using this technique of mechanical insufflation-exsufflation, peak cough expiratory flows can be increased by more than four-fold." The Consensus Panel Report, however, concluded that "[w]hile a variety of nonpharmacologic protussive treatment modalities may improve cough mechanics, clinical studies documenting improvement in patient morbidity and mortality are lacking."

- Motivation to perform any airway clearance technique is key to maintaining pulmonary function. An increase in sputum production, while not necessarily an indicator of improved pulmonary function motivates most patients to continue with their physiotherapy treatment. The ease in which the therapy can be performed by a particular patient is another important consideration. Most adolescent and adult patients who need chest physiotherapy are able to carry out their treatment independently with one of the above methods and using gravity assisted positions and breathing exercises. PEP and the Flutter device are well accepted by children. Long-term comparison of these methods with large groups of patients including the selection of appropriate outcome measures, are needed for further evaluation of the potential success of various methods of airway clearance.
- The Frequencer (Dymedso, Inc., Boisbriand, Quebec, Canada) is a device that provides airway clearance therapy and promotes bronchial drainage by inducing vibration in the chest walls. It induces oscillatory sound waves in the chest by means of an electro-acoustical transducer (referred to as the "Power Head"), which is placed externally on the user's chest. The Power Head is connected to a frequency generator that is capable of producing frequencies between 20 and 100 Hz, and induces sound waves in the user's chest for the purpose of loosening mucus deposits.
- The Frequencer device provides airway clearance by inducing oscillatory sound waves in the chest by means of an electro-acoustical transducer placed externally on the patient's chest. The transducer is connected to a frequency generator which is capable of producing frequencies between 20 and 100Hz. The vibrations in the patient's chest are effective in loosening mucus deposits and promoting bronchial drainage. The Frequencer consists of two parts, a control unit and a transducer. The user places the transducer on the chest. The frequency (adjustable between 20 and 100HZ) and the volume are adjusted in the control unit to create sympathetic resonance that can be felt in the lungs. According to the manufactuer, there are significant differences between other high frequency percussors and the Frequencer
- Specifically: (1) other devices deliver a frequency pounding or striking action, similar to clapping, to a patient's chest to loosen mucus. The Frequencer uses a different operating principle: higher frequency acoustic waves to excite resonance in the chest. (2) Acoustic wave action makes the Frequencer appropriate patients who are: under 3 years of age; elderly and fragile; agitated; immobilized; obese; and status/post surgery.
- Cantin et al (2006) stated that clearance of mucus from airways is the cornerstone of therapy for lung disease in patients with CF. These investigators described the operation of the Frequencer, a novel respiratory physiotherapy device comprised of an electro-acoustical transducer. They hypothesized that the Frequencer would be a safe and effective therapy to help clear secretions from the airways of subjects with CF. A total of 22 individuals with CF were recruited to this study comparing sputum production during conventional chest physiotherapy (CCPT) and Frequencer therapy using a cross-over design.

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- The sputum weight was the main outcome measure. Sputum weight was found to be a reproducible measure
  of the efficacy of chest physiotherapy in individual patients. The Frequencer induced airway clearance in
  patients with CF that was equivalent to that of CCPT. Furthermore, treatment of a 4 % mucin preparation exvivo with the Frequencer significantly reduced the viscosity of the mucin solution as determined in a capillary
  rheometer. The authors concluded that these results indicated the Frequencer is safe and as effective as
  CCPT in inducing airway clearance in patients with CF.
- The American Academy of Neurology's practice parameter update on "The care of the patient with amyotrophic lateral sclerosis" (Miller et al, 2009) noted that "High frequency chest wall oscillation (HFCWO) is unproven for adjunctive airway secretion management".
- McIlwaine et al (2013) noted that PEP is the most commonly used method of airway clearance (AC) in Canada for patients with CF whereas, in some countries, HFCWO is the preferred form of AC. There have been no long-term studies comparing the effectiveness of HFCWO and PEP in the CF population. These investigators determined the long-term effectiveness of HFCWO compared with PEP mask therapy in the treatment of CF as measured by the number of pulmonary exacerbations (PEs). A randomized controlled study was performed in 12 CF centers in Canada. After a 2-month wash-out period, subjects were randomized to perform either HFCWO or PEP mask therapy for 1 year.
- A total of 107 subjects were enrolled in the study; 51 were randomized to PEP and 56 to HFCWO. There were 19 drop-outs within the study period, of which 16 occurred prior to or at the time of randomization. There were significant differences between the groups in the mean number of PEs (1.14 for PEP versus 2.0 for HFCWO) and time to first PE (220 days for PEP versus 115 days for HFCWO, p = 0.02). There was no significant difference in lung function, health-related quality of life scores or patient satisfaction scores between the 2 groups. Positive expiratory pressure mask therapy required a shorter treatment time. The authors concluded that the results of this study favored PEP and do not support the use of HFCWO as the primary form of AC in patients with CF.
- The Impulsator F00012 (Percussionaire Corp, Sandpoint, ID) is an intra-pulmonary percussive ventilator; it is a pneumatic device that delivers high-flow-rate bursts of air and aerosol to the lungs at a frequency of 200 to 300 cycles per minute. Pulsatile breaths are delivered at a peak pressure of 20 to 40 cm H2O, titrated by visualizing percussive movement of the intercostal spaces. Breaths are delivered using a mouthpiece, and the lungs percussed for 5- to 15-second intervals over a 15- to 30-min period. There is a lack of evidence regarding the effectiveness of the Impulsator F00012.
- Kallet (2013) stated that mechanically ventilated patients in respiratory failure often require adjunctive therapies to address special needs such as inhaled drug delivery to alleviate airway obstruction, treat pulmonary infection, or stabilize gas exchange, or therapies that enhance pulmonary hygiene. These therapies generally are supportive in nature rather than curative. Currently, most lack high-level evidence supporting their routine use. In this overview, the author described the rationale and examined the evidence supporting adjunctive therapies during mechanical ventilation. Both mechanistic and clinical research suggests that IPV may enhance pulmonary secretion mobilization and might reverse atelectasis.
- However, its impact on outcomes such as ICU stay is uncertain. The most crucial issue is whether aerosolized antibiotics should be used to treat ventilator-associated pneumonia, particularly when caused by

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multi-drug resistant pathogens. There is encouraging evidence from several studies supporting its use, at least in individual cases of pneumonia non-responsive to systemic antibiotic therapy. Inhaled pulmonary vasodilators provide at least short-term improvement in oxygenation and may be useful in stabilizing pulmonary gas exchange in complex management situations. Small uncontrolled studies suggest aerosolized heparin with N-acetylcysteine might break down pulmonary casts and relieve airway obstruction in patients with severe inhalation injury.

- Similar low-level evidence suggests that heliox is effective in reducing airway pressure and improving ventilation in various forms of lower airway obstruction. These therapies generally are supportive and may facilitate patient management. However, because they have not been shown to improve patient outcomes, it behooves clinicians to use these therapies parsimoniously and to monitor their effectiveness carefully.
- Branson (2013) stated that postoperative pulmonary complications (PPCs) are common and expensive.
   Costs, morbidity, and mortality are higher with PPCs than with cardiac or thromboembolic complications.
   Preventing and treating PPCs is a major focus of respiratory therapists, using a wide variety of techniques and devices, including chest physical therapy, continuous positive airway pressure, incentive spirometry, and IPV. The scientific evidence for these techniques is lacking.

# References

- American Association for Respiratory Care (AARC). AARC clinical practice guidelines. Postural drainage therapy. Respir Care. 1991;36(12):1418-1426.
- Hardy KA, Anderson BD. Noninvasive clearance of airway secretions. Respir Care Clin N Am. 1996;2(2):323-345.
- Houtmeyers E, Gosselink R, Gayan-Ramirez G, et al. Regulation of mucociliary clearance in health and disease. Eur Respir J. 1999;13(5):1177-1188.
- Katkin JP. Cystic fibrosis. In: Conn's Current Therapy 1999. 51st ed. RE Rakel, ed. Philadelphia, PA: W. B. Saunders Co. ;1999.
- American Association for Respiratory Care (AARC). AARC clinical practice guidelines. Directed cough. Respir Care. 1993;38(5):495-499.
- McCool FD, Rosen MJ. Nonpharmacologic airway clearance therapies. ACCP Evidence-Based Clinical Practice Guidelines. Chest. 2006;129:250S-259S. Available at: http://www.chestjournal.org/cgi/content/full/129/1\_suppl/250S. Accessed January 27, 2007.
- Reisman JJ, Rivington-Law B, Corey M, et al. Role of conventional physiotherapy in cystic fibrosis. J Pediatr. 1988;113(4):632-636.
- Thomas J, Cook DJ, Brooks D. Chest physical therapy management of patients with cystic fibrosis. A metaanalysis. Am J Respir Crit Care Med. 1995;151(3 Pt 1):846-850.
- Doring G, Hoiby N; Consensus Study Group. Early intervention and prevention of lung disease in cystic fibrosis: A European consensus. J Cyst Fibros. 2004;3(2):67-91.
- De Boeck K, Vermeulen F, Vreys M, et al. Airway clearance techniques to treat acute respiratory disorders in previously healthy children: Where is the evidence? Eur J Pediatr. 2008;167(6):607-612.

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- Ontario Ministry of Health and Long-Term Care, Medical Advisory Secretariat. Airway clearance devices for cystic fibrosis: An evidence-based analysis. Ontario Health Technology Assessment Series. 2009;9(26).
- Flume PA, Robinson KA, O'Sullivan BP, et al; Clinical Practice Guidelines for Pulmonary Therapies Committee. Cystic fibrosis pulmonary guidelines: Airway clearance therapies. Respir Care. 2009;54(4):522-537.
- National Institutes of Health (NIH), National Heart Lung and Blood Institute. Facts about cystic fibrosis. Information for Patients and the Public. NIH Pub. No. 95-3650. Bethesda, MD: NIH; November 1995. Available at: http://www.nhlbi.nih.gov/health/public/lung/other/cf.htm. Accessed November 26, 2003.
- Cystic Fibrosis Trust. Physiotherapy. Living with CF.London,UK:CysticFibrosisTrust;2004. Available at:http://www.cftrust.org.uk/scope/page/view.go?pageid=64&layout=cftrust. Accessed February 23, 2004.
- Cystic Fibrosis Trust. Physiotherapy forcysticfibrosis.TreatmentInformation.London,UK:CysticFibrosisTrust;1998. Available at:http://www.cftrust.org.uk/scope/page/view.go?pageid=64&layout=cftrust. Accessed February 23, 2004.
- International Cystic Fibrosis Support Group. Physiotherapy in cystic fibrosis. Physiotherapy. New London, CT: International Cystic Fibrosis Support Group; 2003. Available at: http://cf.conncoll.edu/therapy.html. Accessed November 21, 2003.
- Button BM, Heine RG, Catto-Smith AG, et al. Chest physiotherapy in infants with cystic fibrosis: To tip or not? A five-year study. Pediatr Pulmonol. 2003;35(3):208-213.
- British United Provident Association, Health Information Team. Cystic fibrosis. ABC of Health. Mosby Factsheets. London, UK: British United Provident Association; January 2003. Available at: http://hcd2.bupa.co.uk/fact\_sheets/Mosby\_factsheets/Cystic\_fibrosis.html. Accessed November 21, 2003.
- Cystic Fibrosis Trust. FAQs. Meeting point. Parents and carers. Frequently asked questions. London, UK: Cystic Fibrosis Trust; 2003. Available at: http://www.cftrust.org.uk/meeting\_point/faqs\_parents.htm. Accessed November 21, 2003.
- Cedars-Sinai Medical Center. Cystic fibrosis. Medicine on the Horizon. Health InfoCenter. Los Angeles, CA: Cedars-Sinai Medical Center; October 12, 2001. Available at: http://12.31.13.115/healthnews/MedicineontheHorizon/MOTH72001.htm. Accessed November 21, 2003.
- Medical College of Wisconsin. The facts about cystic fibrosis. Medical College of Wisconsin Healthlink. Milwaukee, WI: Medical College of Wisconsin; April 4, 2003. Available at: http://healthlink.mcw.edu/article/1031002233.html. Accessed November 26, 2003.
- Canadian Cystic Fibrosis Foundation (CCFF). Your child and cystic fibrosis. Toronto, ON: CCFF; June 2003. Available at: http://www.cysticfibrosis.ca/pdf/Your\_Child.pdf. Accessed November 26, 2003.
- Merck & Co., Inc. Cystic fibrosis. In: Merck Manual of Medical Information -- Home Edition. 2nd Home ed. MH Beers, ed. Ch. 43, Section 4, Lung and airway disorders. Whitehouse Station, NJ: Merck; 2003. Available at: http://www.merck.com/mrkshared/mmanual\_home/sec4/43.jsp. Accessed November 26, 2003.
- MDAdvice.com. Cystic fibrosis. Rochelle Park, NJ: MDAdvice; 2003. Available at: http://www.mdadvice.com/library/symp/illness125.html. Accessed November 26, 2003.

- University of Chicago Children's Hospital. Breathing Easier. Chicago, IL: University of Chicago Medical Center; 2003. Available at: http://www.ucch.org/ucch/healthpages/pulmcrit/breath/ noframe/daily.html. Accessed November 26, 2003.
- Ohio State University Medical Center, Department of Respiratory Therapy and Department of Women and Infant Nursing. Infant postural drainage and percussion. Patient Education -- Materials. Columbus, OH: Ohio State University Medical Center; July 2002. Available at: http://www.acs.ohiostate.edu/units/osuhosp/patedu/Materials/WomenInfPedIndex.htm. Accessed November 26, 2003.
- Terra RP, Lehnert P. Performing postural drainage and chest percussion for cystic fibrosis. Cystic Fibrosis. In: BCHealthGuideOnLine. Boise, ID: Healthwise, Inc; updated November 26, 2002. Available at: http://www.bchealthguide.org/kbase/as/ug1720/actionset.htm. Accessed November 26, 2003.
- Deborah Heart and Lung Center. Clearing your airway -- postural drainage. General Health Information. Browns Mills, NJ: Deborah Heart and Lung Center; 2003. Available at: http://www.deborah.org/consumer/mca.html. Accessed November 26, 2003.
- Children's Hospital of Eastern Ontario. Airway Clearance Techniques (Chest Physiotherapy) for Immotile Cilia Syndrome. Ottawa, ON: Children's Hospital of Eastern Ontario; 2003. Available at: http://www.cheo.on.ca/english/2013a10.html. Accessed November 26, 2003.
- Medical Network Inc. Chest physical therapy. In: HealthAtoZ. Monmouth Junction, NJ: Medical Network Inc.; 2003. Available at: http://www.healthatoz.com/healthatoz/Atoz/ency/ chest\_physical\_therapy.html. Accessed November 26, 2003.
- Watson A, Pollard K. Physiotherapy. Cystic Fibrosis Online. London, UK: Cystic Fibrosis Medicine; January 2001. Available at: http://www.cysticfibrosismedicine.com/htmldocs/ CFText/physio.htm. Accessed November 26, 2003.
- Muscular Dystrophy Campaign. Chest physiotherapy. Care. Information Library. London, UK: Muscular Dystrophy Campaign; 2003. Available at: http://www.muscular-dystrophy.org/information/Care/smapt5.html. Accessed November 26, 2003.
- Canadian Lung Association. Bronchiectasis. Diseases A-Z. Ottawa, ON: Canadian Lung Association; 2003. Available at: http://www.lung.ca/diseases/bronchiectasis.html. Accessed November 26, 2003.
- American Association for Respiratory Care (AARC), Bronchial Drainage Advisory Committee. Postural drainage therapy. AARC Clinical Practice Guideline. Respir Care. 1991;36:1418-1426. Available at: http://www.rcjournal.com/online\_resources/cpgs/pdtcpg.html. Accessed February 23, 2004.
- American Association of Respiratory Care (AARC). Suctioning of the patient in the home. AARC Clinical Practice Guideline. Respir Care. 1999:44(1):99-104. Available at: http://www.rcjournal.com/online\_resources/cpgs/sotpithcpg.html. Accessed February 23, 2004.
- Flenady VJ, Gray PH. Chest physiotherapy for preventing morbidity in babies being extubated from mechanical ventilation. Cochrane Database Syst Rev. 2002;(2):CD000283.
- Perrotta C, Ortiz Z, Roque M. Chest physiotherapy for acute bronchiolitis in paediatric patients between 0 and 24 months old. Cochrane Database Syst Rev. 2007;(1):CD004873.
- McIlwaine M. Physiotherapy and airway clearance techniques and devices. Paediatr Respir Rev. 2006;7 Suppl 1:S220-S222.

#### AC-AECHE092011 Page **12** of **22** Copyright 2016 No part of this document may be reproduced without permission

- van der Schans CP. Conventional chest physical therapy for obstructive lung disease. Respir Care. 2007;52(9):1198-1206; discussion 1206-1209.
- Hough JL, Flenady V, Johnston L, Woodgate PG. Chest physiotherapy for reducing respiratory morbidity in infants requiring ventilatory support. Cochrane Database Syst Rev. 2008;(3):CD006445.
- Advanced Respiratory. The Vest Airway Clearance System [website]. St. Paul, MN: Advanced Respiratory; 2003. Available at: http://www.abivest.com/. Accessed February 28, 2003.
- Whitman J, Van Beusekom R, Olson S, et al. Preliminary evaluation of high-frequency chest compression for secretion clearance in mechanically ventilated patients. Respir Care. 1992;38(10):1081-1087.
- Langenderfer B. Alternatives to percussion and postural drainage. A review of mucus clearance therapies: Percussion and postural drainage, autogenic drainage, positive expiratory pressure, flutter valve, intrapulmonary percussive ventilation, and high-frequency chest compression with the ThAIRapy Vest. J Cardiopulm Rehabil. 1998;18(4):283-289.
- Oermann CM, Sockrider MM, Giles D, et al. Comparison of high-frequency chest wall oscillation and oscillating positive expiratory pressure in the home management of cystic fibrosis: A pilot study. Pediatr Pulmonol. 2001;32(5):372-377.
- Pryor JA. Physiotherapy for airway clearance in adults. Eur Respir J. 1999;14(6):1418-1424.
- Hess DR. The evidence for secretion clearance techniques. Respir Care. 2002;46(11):1276-1293.
- Jones AP, Rowe BH. Bronchopulmonary hygiene physical therapy for chronic obstructive pulmonary disease and bronchiectasis. Cochrane Database Syst Rev. 1998;(4):CD000045.
- Goss CH. Airway clearance in cystic fibrosis. Respir Care. 2003;48(1):20-21.
- van der Schans C, Prasad A, Main E. Chest physiotherapy compared to no chest physiotherapy for cystic fibrosis. Cochrane Database Syst Rev. 2000;(2):CD001401.
- Main E, Prasad A, van der Schans C. Conventional chest physiotherapy compared to other forms of chest physiotherapy for cystic fibrosis. Cochrane Database Syst Rev. 2005;(1):CD002011.
- Plioplys AV, Lewis S, Kasnicka I. Pulmonary vest therapy in pediatric long-term care. J Am Med Dir Assoc. 2002;3(5):318-321.
- Dosman CF, Zuberbuhler PC, Tabak JI, Jones RL. Effects of positive end-expiratory pressure on oscillated volume during high frequency chest compression in children with cystic fibrosis. Can Respir J. 2003;10(2):94-98.
- Braverman JM. Increasing the quantity of lungs for transplantation using high-frequency chest wall oscillation: A proposal. Prog Transplant. 2002;12(4):266-274.
- Davidson KL. Airway clearance strategies for the pediatric patient. Respir Care. 2002;47(7):823-828.
- Fink JB, Mahlmeister MJ. High-frequency oscillation of the airway and chest wall. Respir Care. 2002;47(7):797-807.
- Scholz SE, Sticher J, Haufler G, et al. Combination of external chest wall oscillation with continuous positive airway pressure. Br J Anaesth. 2001;87(3):441-446.
- Scherer TA, Barandun J, Martinez E, et al. Effect of high-frequency oral airway and chest wall oscillation and conventional chest physical therapy on expectoration in patients with stable cystic fibrosis. Chest. 1998;113(4):1019-1027.

#### AC-AECHE092011 Page **13** of **22** Copyright 2016 No part of this document may be reproduced without permission

- Kluft J, Beker L, Castagnino M, et al. A comparison of bronchial drainage treatments in cystic fibrosis. Pediatr Pulmonol. 1996;22(4):271-274.
- Silverman E, Ebright L, Kwiatkowski M, Cullina J. Current management of bronchiectasis: Review and 3 case studies. Heart Lung. 2003;32(1):59-64
- Butler S, O'Neill B. High frequency chest compression therapy: A case study. Pediatr Pulmonol. 1995;19(1):56-59.
- Braggion C, Cappelletti LM, Cornacchia M, et al. Short-term effects of three chest physiotherapy regimens in patients hospitalized for pulmonary exacerbations of cystic fibrosis: A cross-over randomized study. Pediatr Pulmonol. 1995;19(1):16-22.
- Arens R, Gozal D, Omlin KJ, et al. Comparison of high frequency chest compression and conventional chest physiotherapy in hospitalized patients with cystic fibrosis. Am J Respir Crit Care Med. 1994;150(4):1154-1157.
- Warwick WJ, Hansen LG. The long-term effect of high-frequency chest compression therapy on pulmonary complications of cystic fibrosis. Pediatr Pulmonol. 1991;11(3):265-271.
- Hansen LG, Warwick WJ. High-frequency chest compression system to aid in clearance of mucus from the lung. Biomed Instrum Technol. 1990;24(4):289-294.
- Phillips GE, Pike SE, Jaffe A, Bush A. Comparison of active cycle of breathing and high-frequency oscillation jacket in children with cystic fibrosis. Pediatr Pulmonol. 2004;37(1):71-75.
- Varekojis SM, Douce FH, Flucke RL, et al. A comparison of the therapeutic effectiveness of and preference for postural drainage and percussion, intrapulmonary percussive ventilation, and high-frequency chest wall compression in hospitalized cystic fibrosis patients. Respir Care. 2003;48(1):24-28.
- Giarraffa P, Berger KI, Chaikin AA, et al. Assessing efficacy of high-frequency chest wall oscillation in patients with familial dysautonomia. Chest. 2005;128(5):3377-3381.
- Darbee JC, Kanga JF, Ohtake PJ. Physiologic evidence for high-frequency chest wall oscillation and positive expiratory pressure breathing in hospitalized subjects with cystic fibrosis. Phys Ther. 2005;85(12):1278-1289.
- Dosman CF, Jones RL. High-frequency chest compression: A summary of the literature. Can Respir J. 2005;12(1):37-41.
- Warwick WJ, Wielinski CL, Hansen LG. Comparison of expectorated sputum after manual chest physical therapy and high-frequency chest compression. Biomed Instrum Technol. 2004;38(6):470-475.
- Spencer S, Evans D, Milan SJ. Oscillating devices for airway clearance in people with cystic fibrosis (Protocol for Cochrane Review). Cochrane Database Syst Rev. 2005;(3):CD005407.
- Stites SW, Perry GV, Peddicord T, et al. Effect of high-frequency chest wall oscillation on the central and peripheral distribution of aerosolized diethylene triamine penta-acetic acid as compared to standard chest physiotherapy in cystic fibrosis. Chest. 2006;129(3):712-717.
- Lange DJ, Lechtzin N, Davey C, et al.; HFCWO Study Group. High-frequency chest wall oscillation in ALS: An exploratory randomized, controlled trial. Neurology. 2006;67(6):991-997.
- Chaisson KM, Walsh S, Simmons Z, Vender RL. A clinical pilot study: High frequency chest wall oscillation airway clearance in patients with amyotrophic lateral sclerosis. Amyotroph Lateral Scler. 2006;7(2):107-111.
- Chatburn RL. High-frequency assisted airway clearance. Respir Care. 2007;52(9):1224-1237.

AC-AECHE092011 Page **14** of **22** Copyright 2016 No part of this document may be reproduced without permission

- Kempainen RR, Williams CB, Hazelwood A, et al. Comparison of high-frequency chest wall oscillation with differing waveforms for airway clearance in cystic fibrosis. Chest. 2007;132(4):1227-1232.
- Drosman CF, Jones RL. High-frequency chest compression: A summary of the literature. Can Respir J. 2005;12(1):37-41.
- NHIC, Inc. LCD for high frequency chest wall oscillation devices (L12870). Local Coverage Determination (LCD) ID. No. L12870. Durable Medical Equipment Medicare Administrative Contractor (DME MAC) Jurisdiction A. Hingham, MA: NHIC; October 1, 2008.
- Morrison L, Agnew J. Oscillating devices for airway clearance in people with cystic fibrosis. Cochrane Database Syst Rev. 2009;(1):CD006842.
- Morrison L, Agnew J. Oscillating devices for airway clearance in people with cystic fibrosis. Cochrane Database Syst Rev. 2009;(1):CD006842.
- Homnick DN, White F, de Castro C. Comparison of effects of an intrapulmonary percussive ventilator to standard aerosol and chest physiotherapy in treatment of cystic fibrosis. Pediatr Pulmonol. 1995;20(1):50-55.
- Deakins K, Chatburn RL. A comparison of intrapulmonary percussive ventilation and conventional chest physiotherapy for the treatment of atelectasis in the pediatric patient. Respir Care. 2002;47(10):1162-1167.
- Newhouse PA, White F, Marks JH, Homnick DN. The intrapulmonary percussive ventilator and flutter device compared to standard chest physiotherapy in patients with cystic fibrosis. Clin Pediatr (Phila). 1998;37(7):427-432.
- Hardy KA, Anderson BD. Noninvasive clearance of airway secretions. Respir Care Clin N Am. 1996;2(2):323-345.
- Natale JE, Pfeifle J, Homnick DN. Comparison of intrapulmonary percussive ventilation and chest physiotherapy. A pilot study in patients with cystic fibrosis. Chest. 1994;105(6):1789-1793.
- Toussaint M, De Win H, Steens M, Soudon P. Effect of intrapulmonary percussive ventilation on mucus clearance in duchenne muscular dystrophy patients: A preliminary report. Respir Care. 2003;48(10):940-947.
- Varekojis SM, Douce FH, Flucke RL, et al. A comparison of the therapeutic effectiveness of and preference for postural drainage and percussion, intrapulmonary percussive ventilation, and high-frequency chest wall compression in hospitalized cystic fibrosis patients. Respir Care. 2003;48(1):24-28.
- Pryor JA. Physiotherapy for airway clearance in adults. Eur Respir J. 1999;14(6):1418-1424.
- Langenderfer B. Alternatives to percussion and postural drainage. A review of mucus clearance therapies: Percussion and postural drainage, autogenic drainage, positive expiratory pressure, flutter valve, intrapulmonary percussive ventilation, and high-frequency chest compression with the ThAIRapy Vest. J Cardiopulm Rehabil. 1998;18(4):283-289.
- Birnkrant DJ, Pope JF, Lewarski J, et al. Persistent pulmonary consolidation treated with intrapulmonary percussive ventilation: A preliminary report. Pediatr Pulmonol. 1996;21(4):246-249.
- Vargas F, Bui HN, Boyer A, et al. Intrapulmonary percussive ventilation in acute exacerbations of COPD patients with mild respiratory acidosis: A randomized controlled trial [ISRCTN17802078]. Crit Care. 2005;9(4):R382-R389.
- Reardon CC, Christiansen D, Barnett ED, Cabral HJ. Intrapulmonary percussive ventilation vs incentive spirometry for children with neuromuscular disease. Arch Pediatr Adolesc Med. 2005;159(6):526-531.

AC-AECHE092011 Page **15** of **22** Copyright 2016 No part of this document may be reproduced without permission

- Reychler G, Keyeux A, Cremers C, et al. Comparison of lung deposition in two types of nebulization: Intrapulmonary percussive ventilation vs jet nebulization. Chest. 2004;125(2):502-508.
- Reychler G, Wallemacq P, Rodenstein DO, et al. Comparison of lung deposition of amikacin by intrapulmonary percussive ventilation and jet nebulization by urinary monitoring. J Aerosol Med. 2006;19(2):199-207.
- Branson RD. Secretion management in the mechanically ventilated patient. Respir Care. 2007;52(10):1328-1342; discussion 1342-1347.
- Brückner U. Oscillating physiotherapy for secretolysis. Pneumologie. 2008;62 Suppl 1:S31-S34.
- Gondor M, Nixon PA, Mutich R, et al. Comparison of flutter device and chest physical therapy in the treatment of cystic fibrosis pulmonary exacerbation. Pediatr Pulmonol. 1999;28(4):255-260.
- Homnick DN, Anderson K, Marks JH. Comparison of the flutter device to standard chest physiotherapy in hospitalized patients with cystic fibrosis: A pilot study. Chest. 1998:114(4):993-997.
- Burioka N, Sugimoto Y, Suyama H, et al. Clinical efficacy of the FLUTTER device for airway mucus clearance in patients with diffuse panbronchiolitis. Respirology. 1998;3(3):183-186.
- App EM, Kieselmann R, Reinhardt D, et al. Sputum rheology changes in cystic fibrosis lung disease following two different types of physiotherapy: Flutter vs autogenic drainage. Chest. 1998:114(1):171-177.
- Padman R, Geuouque DM, Engelhardt MT. Effects of the flutter device on pulmonary function studies among pediatric cystic fibrosis patients. Del Med J. 1999;71(1):13-18.
- Konstanz M. Efficacy of the Flutter device for airway clearance in patients with cystic fibrosis. J Pediatr. 1994;124(5 Pt 1):689-693.
- Pryor JA, Webber BA, Hodson ME, et al. The Flutter VRP1 as an adjunct to chest physiotherapy in cystic fibrosis. Respir Med. 1994;88(9):677-681.
- Newhouse PA, White F, Marks JH, et al. The intrapulmonary percussive ventilator and flutter device compared to standard chest physiotherapy in patients with cystic fibrosis. Clin Pediatr (Phila). 1998;37(7):427-432.
- Van Wined CM, Visser A, Hop W, et al. Effects of flutter and PEP mask physiotherapy on symptoms and lung function in children with cystic fibrosis. Eur Respir J. 1998;12(1):143-147.
- Fink JB, Mahlmeister MJ. High-frequency oscillation of the airway and chest wall. Respir Care. 2002;47(7):797-807.
- Thompson CS, Harrison S, Ashley J, et al. Randomised crossover study of the Flutter device and the active cycle of breathing technique in non-cystic fibrosis bronchiectasis. Thorax. 2002;57(5):446-448.
- Bellone A, Fasciolo R, Rasch S, et al. Chest physical therapy in patients with acute exacerbation of chronic bronchitis: Effectiveness of three methods. Arch Phys Med Rehabil. 2000;81(5):558-560.
- Volsko TA, Deiform J, Chatburn RL. Performance comparison of two oscillating positive expiratory pressure devices: Acapella versus Flutter. Respir Care. 2003;48(2):124-130.
- McIlwaine PM, Wong LT, Peacock D, Davidson AG. Long-term comparative trial of positive expiratory pressure versus oscillating positive expiratory pressure (flutter) physiotherapy in the treatment of cystic fibrosis. J Pediatr. 2001;138(6):845-850.

### AC-AECHE092011 Page **16** of **22** Copyright 2016 No part of this document may be reproduced without permission

- Langenderfer B. Alternatives to percussion and postural drainage. A review of mucus clearance therapies: Percussion and postural drainage, autogenic drainage, positive expiratory pressure, flutter valve, intrapulmonary percussive ventilation, and high-frequency chest compression with the ThAIRapy Vest. J Cardiopulm Rehabil. 1998;18(4):283-289.
- Girard JP, Terki N. The Flutter VRP1: A new personal pocket therapeutic device used as an adjunct to drug therapy in the management of bronchial asthma. J Investig Allergol Clin Immunol. 1994;4(1):23-27.
- Swift GL, Rainer T, Saran R, et al. Use of flutter VRP1 in the management of patients with steroid-dependent asthma. Respiration. 1994;61(3):126-129.
- Leru P, Bistriceanu G, Ibraim E, Stoicescu P. Flutter-VRP1 Desitin--a new physiotherapeutic device for the treatment of chronic obstructive bronchitis. Rom J Intern Med. 1994;32(4):315-320.
- Wolkove N, Kamel H, Rotaple M, Baltzan MA Jr. Use of a mucus clearance device enhances the bronchodilator response in patients with stable COPD. Chest. 2002;121(3):702-707.
- Patterson JE, Bradley JM, Hewitt O, et al. Airway clearance in bronchiectasis: A randomized crossover trial of active cycle of breathing techniques versus Acapella. Respiration. 2005;72(3):239-242.
- Patterson JE, Hewitt O, Kent L, et al. Acapella versus 'usual airway clearance' during acute exacerbation in bronchiectasis: A randomized crossover trial. Chron Respir Dis. 2007;4(2):67-74.
- Tonesen P, Stovring S. Positive expiratory pressure (PEP) as lung physiotherapy in cystic fibrosis: A pilot study. Eur J Respir Dis. 1984;65(6):419-422.
- Groth S, Stafanger G, Dirkesen H, et al. Positive expiratory pressure (PEP-mask) physiotherapy improves ventilation and reduces volume of trapped gas in cystic fibrosis. Bull Eur Physiopatho Respir. 1985;21(4):339-343.
- Mortensen J, Falk M, Groth S, et al. The effects of postural drainage and positive expiratory pressure physiotherapy on tracheobronchial clearance in cystic fibrosis. Chest. 1991;100(5):1350-1357.
- Oberwaldner B, Evans JC, Zach MS. Forced expirations against a variable resistance: A new chest physiotherapy method in cystic fibrosis. Pediatr Pulmonol. 1986:2(6):358-367.
- Tyrrell JC, Hiller EJ, Martin J. Face mask physiotherapy in cystic fibrosis. Arch Dis Child. 1986:61(6):598-600.
- Steen HJ, Redmond AO, O'Neill D, et al. Evaluation of the PEP mask in cystic fibrosis. Acta Paediatr Scand. 1991;80(1):51-56.
- Oberwaldner B, Theissl B, Rucker A, et al. Chest physiotherapy in hospitalized patients with cystic fibrosis: A study of lung function effects and sputum production. Eur Respir J. 1991;4(2):152-158.
- Van Asperen PP, Jackson L, Hennessy P, et al. Comparison of a positive expiratory pressure (PEP) mask with postural drainage in patients with cystic fibrosis. Aust Paediatr J. 1987;23(5):283-284.
- Pfleger A, Theissl B, Oberwaldner B, et al. Self-administered chest physiotherapy in cystic fibrosis: A comparative study of high-pressure PEP and autogenic drainage. Lung. 1992;170(6):323-330.
- Van der Schans CP, van der Mark TW, de Vries G, et al. Effect of positive expiratory pressure breathing in patients with cystic fibrosis. Thorax. 1991:46(4):252-256.
- Hofmeyr JL, Webber BA, Hodson ME. Evaluation of positive expiratory pressure as an adjunct to chest physiotherapy in the treatment of cystic fibrosis. Thorax. 1986;41(12):951-954.

### AC-AECHE092011 Page **17** of **22** Copyright 2016 No part of this document may be reproduced without permission

- Braggion C, Cappelletti LM, Cornacchia M, et al. Short-term effects of three chest physiotherapy regimens in patients hospitalized for pulmonary exacerbations of cystic fibrosis: A cross-over randomized study. Pediatr Pulmonol. 1995;19(1):16-22.
- Van Hengstum M, Festen J, Beurskens C, et al. Effect of positive expiratory pressure mask physiotherapy (PEP) versus forced expiration technique (FET/PD) on regional lung clearance in chronic bronchitis. Eur Respir J. 1991:4(6):651-654.
- McIlwaine PM, Wong LT, Peacock D, et al. Long-term comparative trial of conventional postural drainage and percussion versus positive expiratory pressure physiotherapy in the treatment of cystic fibrosis. J Pediatr. 1997;131(4):570-574.
- van Winden CM, Visser A, Hop W, et al. Effects of flutter and PEP mask physiotherapy on symptoms and lung function in children with cystic fibrosis. Eur Respir J. 1998;12(1):143-147.
- Volsko TA, Chatburn RL. Performance comparison of two oscillating positive expiratory pressure devices: Acapella versus flutter. Respir Care. 2003;48(2):124-130.
- Ambrosino N, Callegari G, Galloni C, et al. Clinical evaluation of oscillating positive airway pressure for enhancing expectoration in diseases other than cystic fibrosis. Monaldi Arch Chest Dis. 1995;50(4):269-275.
- Bellone A, Spagnolatti L, Massobrio M, et al. Short-term effects of expiration under positive pressure in patients with acute exacerbation of chronic obstructive pulmonary disease and mild acidosis requiring non-invasive positive pressure ventilation. Intensive Care Med. 2002;28(5):581-585.
- Gremmo ML, Guenza MC. Positive expiratory pressure in the physiotherapeutic management of primary ciliary dyskinesia in paediatric age. Monaldi Arch Chest Dis. 1999;54(3):255-257.
- National Institute for Clinical Excellence (NICE). Chronic obstructive pulmonary disease (COPD). Full Guideline, Second Consultation. London, UK: NICE; October 2003. Available at: http://www.nice.org.uk/Docref.asp?d=92319. Accessed January 2004.
- Bradley JM, Moran FM, Stuart Elborn J. Evidence for physical therapies (airway clearance and physical training) in cystic fibrosis: An overview of five Cochrane systematic reviews. Respir Med. 2006;100(2):191-201.
- Laube BL, Geller DE, Lin TC, et al. Positive expiratory pressure changes aerosol distribution in patients with cystic fibrosis. Respir Care. 2005;50(11):1438-1444.
- Lagerkvist AL, Sten G, Westerberg B, et al. Positive expiratory pressure (PEP) treatment in children with multiple severe disabilities. Acta Paediatr. 2005;94(5):538-542.
- Darbee JC, Ohtake PJ, Grant BJ, Cerny FJ. Physiologic evidence for the efficacy of positive expiratory pressure as an airway clearance technique in patients with cystic fibrosis. Phys Ther. 2004;84(6):524-537.
- Elkins MR, Jones A, van der Schans C. Positive expiratory pressure physiotherapy for airway clearance in people with cystic fibrosis. Cochrane Database Syst Rev. 2006;(2):CD003147.
- Lagerkvist AL, Sten GM, Redfors SB, et al. Immediate changes in blood-gas tensions during chest physiotherapy with positive expiratory pressure and oscillating positive expiratory pressure in patients with cystic fibrosis. Respir Care. 2006;51(10):1154-1161.

- Placidi G, Cornacchia M, Polese G, et al. Chest physiotherapy with positive airway pressure: A pilot study of short-term effects on sputum clearance in patients with cystic fibrosis and severe airway obstruction. Respir Care. 2006;51(10):1145-1153.
- Su CL, Chiang LL, Chiang TY, et al. Domiciliary positive expiratory pressure improves pulmonary function and exercise capacity in patients with chronic obstructive pulmonary disease. J Formos Med Assoc. 2007;106(3):204-211.
- Sehlin M, Ohberg F, Johansson G, Winsö O. Physiological responses to positive expiratory pressure breathing: A comparison of the PEP bottle and the PEP mask. Respir Care. 2007;52(8):1000-1005.
- Myers TR. Positive expiratory pressure and oscillatory positive expiratory pressure therapies. Respir Care. 2007;52(10):1308-1327.
- Bach JR. Mechanical exsufflation, noninvasive ventilation and new strategies for pulmonary rehabilitation and sleep disordered breathing. Bull NY Acad Med. 1992;68(2):321-340.
- Bach JR, Smith WH, Michaels J, et al. Airway secretion clearance by mechanical exsufflation for postpoliomyelitis ventilator-assisted individuals. Arch Phys Med Rehabil. 1993;74(2):170-177.
- Bach JR. Mechanical insufflation-exsufflation. Comparison of peak expiratory flows with manually assisted and unassisted coughing techniques. Chest. 1993;104(5):1553-62.
- Bach JR. Update and perspectives on noninvasive respiratory muscle aids, Part 1: The inspiratory aids. Chest. 1994;105(4):1230-1240.
- Bach JR. Update and perspective on noninvasive respiratory muscle aids. Part 2: The expiratory aids. Chest. 1994;105(5):1538-1544.
- Bach JR. Amyotrophic lateral sclerosis: Predictors for prolongation of life by noninvasive respiratory aids. Arch Phys Med Rehabil. 1995;76(9):828-832.
- Bach JR. Prevention of morbidity and mortality with the use of physical medicine aids. In: Pulmonary Rehabilitation: The Obstructive and Paralytic Conditions. JR Bach, ed. Philadelphia, PA: Hanley & Belfus; 1996.
- Hanayama K, Ishikawa Y, Bach JR. Amyotrophic lateral sclerosis. Successful treatment of mucous plugging by mechanical insufflation-exsufflation. Am J Phys Med Rehabil. 1997;76(4):338-339.
- Bach JR, Ishikawa Y, Kim H. Prevention of pulmonary morbidity for patients with Duchenne muscular dystrophy. Chest. 1997;112(4):1024-1028.
- Bach JR, Niranjan V, Weaver B. Spinal muscular atrophy type 1. Noninvasive respiratory management approach. Chest. 2000;117(4):1100-1105.
- Kang SW, Bach JR. Maximum insufflation capacity: Vital capacity and cough flows in neuromuscular disease. Am J Phys Med Rehab. 2000;79(3):222-227.
- Bach JR, Kang SW. Disorders of ventilation: Weakness, stiffness, and mobilization [editorial]. Chest. 2000;117(2):301-303.
- Bach JR, Wang T. Noninvasive long-term ventilatory support for individuals with spinal muscular atrophy and functional bulbar musculature. Arch Phys Med Rehabil. 1995;76(3):213-217.
- Bach JR. Respiratory muscle aids for the prevention of pulmonary morbidity and mortality. Semin Neurol. 1995;15(1):72-81.

#### AC-AECHE092011 Page **19** of **22** Copyright 2016 No part of this document may be reproduced without permission

- Bach JR. Mechanical insufflation/exsufflation: has it come of age? A commentary. Eur Respir J. 2003;21(3):385-386.
- Dean S, Bach JR. The use of noninvasive respiratory muscle aids in the management of patients with progressive neuromuscular diseases. Respir Care Clin N Am. 1996;2(2):223-240.
- Castro C, Bach JR. Mechanical insufflation. Thorax. 2002;57(3):281.
- Tzeng AC, Bach JR. Prevention of pulmonary morbidity for patients with neuromuscular disease. Chest. 2000;118(5):1390-1396.
- Gomez-Merino E, Sancho J, Marin J, et al. Mechanical insufflation-exsufflation: Pressure, volume, and flow relationships and the adequacy of the manufacturer's guidelines. Am J Phys Med Rehabil. 2002;81(8):579-583.
- Birnkrant DJ, Pope JF, Eiben RM. Management of the respiratory complications of neuromuscular diseases in the pediatric intensive care unit. J Child Neurol. 1999;14(3):139-143.
- TriCenturion, LLC. Mechanical in-exsufflation devices. Medicare Draft Local Medical Review Guideline. DMERC Region A. Columbia, SC: TriCenturion; October 25, 2002.
- Sivasothy P. Effect of manually assisted cough and mechanical insufflation on cough flow of normal subjects, patients with chronic obstructive pulmonary disease (COPD), and patients with respiratory muscle weakness. Thorax. 1993; 56(6):438-444.
- Irwin RS, Boulet LP, Cloutier MM, et al. Managing cough as a defense mechanism and as a symptom. A consensus panel report of the American College of Chest Physicians. Chest. 1998;114(2 Suppl Managing):133S-181S.
- Lahrmann H, Wild M, Zdrahal F, Grisold W. Expiratory muscle weakness and assisted cough in ALS. Amyotroph Lateral Scler Other Motor Neuron Disord. 2003;4(1):49-51.
- Sancho J, Servera E, Diaz J, Marin J. Efficacy of mechanical insufflation-exsufflation in medically stable patients with amyotrophic lateral sclerosis. Chest. 2004;125(4):1400-1405.
- Mustfa N, Aiello M, Lyall RA, et al. Cough augmentation in amyotrophic lateral sclerosis. Neurology. 2003 11;61(9):1285-1287.
- Sancho J, Servera E, Vergara P, Marin J. Mechanical insufflation-exsufflation vs. tracheal suctioning via tracheostomy tubes for patients with amyotrophic lateral sclerosis: A pilot study. Am J Phys Med Rehabil. 2003;82(10):750-753.
- Servera E, Sancho J, Gomez-Merino E, et al. Non-invasive management of an acute chest infection for a patient with ALS. J Neurol Sci. 2003;209(1-2):111-113.
- Chatwin M, Ross E, Hart N, et al. Cough augmentation with mechanical insufflation/exsufflation in patients with neuromuscular weakness. Eur Respir J. 2003;21(3):502-508.
- Miske LJ, Hickey EM, Kolb SM, et al. Use of the mechanical in-exsufflator in pediatric patients with neuromuscular disease and impaired cough. Chest. 2004;125(4):1406-1412.
- Pillastrini P, Bordini S, Bazzocchi G, et al. Study of the effectiveness of bronchial clearance in subjects with upper spinal cord injuries: Examination of a rehabilitation programme involving mechanical insufflation and exsufflation. Spinal Cord. 2006;44(10):614-616.

### AC-AECHE092011 Page **20** of **22** Copyright 2016 No part of this document may be reproduced without permission

- Vianello A, Corrado A, Arcaro G, et al. Mechanical insufflation-exsufflation improves outcomes for neuromuscular disease patients with respiratory tract infections. Am J Phys Med Rehabil. 2005;84(2):83-91.
- Winck JC, Goncalves MR, Lourenco C, et al. Effects of mechanical insufflation-exsufflation on respiratory parameters for patients with chronic airway secretion encumbrance. Chest. 2004;126(3):774-780.
- Anderson JL, Hasney KM, Beaumont NE. Systematic review of techniques to enhance peak cough flow and maintain vital capacity in neuromuscular disease: The case for mechanical insufflation-exsufflation. Phys Ther Rev. 2005;10(1):25-33.
- Liszner K, Feinberg M. Cough assist strategy for pulmonary toileting in ventilator-dependent spinal cord injured patients. Rehabil Nurs. 2006;31(5):218-221.
- Homnick DN. Mechanical insufflation-exsufflation for airway mucus clearance. Respir Care. 2007;52(10):1296-1307.
- Fauroux B, Guillemot N, Aubertin G, et al. Physiologic benefits of mechanical insufflation-exsufflation in children with neuromuscular diseases. Chest. 2008;133(1):161-168.
- Schmidt I. Assisted cough--physiotherapy to improve expectoration of mucus. Pneumologie. 2008;62 Suppl 1:S23-S27.
- Tang CY, Taylor NF, Blackstock FC. Chest physiotherapy for patients admitted to hospital with an acute exacerbation of chronic obstructive pulmonary disease (COPD): A systematic review. Physiotherapy. 2010;96(1):1-13.
- Yang Ming, Yan Yuping, Yin Xiangli, et al. Chest physiotherapy for pneumonia in adults. Cochrane Database Syst Rev. 2010;(2):CD006338.
- Cross J, Elender F, Barton G, et al. A randomised controlled equivalence trial to determine the effectiveness and cost utility of manual chest physiotherapy techniques in the management of exacerbations of chronic obstructive pulmonary disease (MATREX). Health Technol Assess. 2010;14(23):1-176.
- Yuan N, Kane P, Shelton K, et al. Safety, tolerability, and efficacy of high-frequency chest wall oscillation in pediatric patients with cerebral palsy and neuromuscular diseases: An exploratory randomized controlled trial. J Child Neurol. 2010;25(7):815-821.
- Cantin AM, Bacon M, Berthiaume Y. Mechanical airway clearance using the frequencer electro-acoustical transducer in cystic fibrosis. Clin Invest Med. 2006;29(3):159-165.
- U.S. Food and Drug Administration (FDA), Center for Devices and Radiologic Health (CDRH). RespIn11 Model Powered Precursory. RespInnovation SAS, Seillans, France. Premarket Notification 510(k) No. K121170. Rockville, MD: FDA; July 13, 2012.
- Miller RG, Jackson CE, Kasarskis EJ, et al; Quality Standards Subcommittee of the American Academy of Neurology. Practice parameter update: The care of the patient with amyotrophic lateral sclerosis: Drug, nutritional, and respiratory therapies (an evidence-based review): Report of the Quality Standards Subcommittee of the American Academy of Neurology. Neurology. 2009;73(15):1218-1226. Available at: http://www.guideline.gov/content.aspx?id=15953&search=mechanical+in-exsufflation+. Accessed January 6, 2014.
- Nicolini A, Cardini F, Landucci N, et al. Effectiveness of treatment with high-frequency chest wall oscillation in patients with bronchiectasis. BMC Pulm Med. 2013;13:21.

# AC-AECHE092011 Page **21** of **22** Copyright 2016 No part of this document may be reproduced without permission

- McIlwaine MP, Alarie N, Davidson GF, et al. Long-term multicentre randomised controlled study of high frequency chest wall oscillation versus positive expiratory pressure mask in cystic fibrosis. Thorax. 2013;68(8):746-751.
- Dimassi S, Vargas F, Lyazidi A, et al. Intrapulmonary percussive ventilation superimposed on spontaneous breathing: A physiological study in patients at risk for extubation failure. Intensive Care Med. 2011;37(8):1269-1276.
- Kallet RH. Adjunct therapies during mechanical ventilation: Airway clearance techniques, therapeutic aerosols, and gases. Respir Care. 2013;58(6):1053-1073.
- Branson RD. The scientific basis for postoperative respiratory care. Respir Care. 2013;58(11):1974-1984.
- Fagevik Olsen M, Westerdahl E. Positive expiratory pressure in patients with chronic obstructive pulmonary disease: A systematic review. Respiration. 2009;77(1):110-118.
- Orman J, Westerdahl E. Chest physiotherapy with positive expiratory pressure breathing after abdominal and thoracic surgery: A systematic review. Acta Anaesthesiologica Scandinavica. 2010;54(3):261-267.
- Chatwin M, Bush A, Simonds AK. Outcome of goal-directed non-invasive ventilation and mechanical insufflation/exsufflation in spinal muscular atrophy type I. Arch Dis Child. 2011;96(5):426-432.

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