

High Frequency Chest Wall Oscillation (HFCWO) for Neuromuscular Patients with Airway Clearance Needs:

A Case for Reimbursement

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Introduction

Airway clearance (AC) describes a range of therapeutic activities with a common goal of clearing airways of secretions and other debris in individuals who have pulmonary disease or respiratory impairment or are at risk for developing either of those conditions. The AC techniques include the application of various physical maneuvers using the hands or appropriate equipment. The procedures may be applied by one of many health care professionals, by an educated family member, or by the patient in an effort to maintain patent and clear airways. The ultimate clinical outcomes of AC include enhancing ventilation, reducing airway obstruction and diminishing the risk of continuing or new infections of the respiratory tract. The latter outcome is important for individuals with chronic respiratory disease and for those with respiratory impairment secondary to some neuromuscular process. Neuromuscular disease often results in respiratory muscle weakness and a heightened risk of pneumonia and other infections by virtue of an inability to cough effectively to remove accumulated secretions.

Airway clearance has developed throughout the 20th century, originating in England, and began within the disciplines of nursing and physical therapy. Indeed, until the 1980's AC techniques were known throughout the health professions as "chest physical therapy", "chest PT", "chest physiotherapy", or simply "physio".

Historically, the medical profession has recognized the importance of and large amount of time, burden and financial resources inherent in providing airway clearance. Several major "state of the art" reviews have appeared in the literature over the past quarter century.^{1,2,3} At least two professions – respiratory therapy and physical therapy - have promulgated standards of practice regarding skills found in airway clearance.^{4,5}

Interdisciplinary educational efforts that incorporate the professions involved in airway clearance have obtained Federal funding (Medicare) status in past decades. Finally, more than "...two generations of physicians have been taught that retention of excessive secretions in the respiratory tract is not only bad for pulmonary function but can also be lethal to the patient."²

Airway Clearance in Cystic Fibrosis

Of all the diseases and conditions for which airway clearance offers therapeutic benefits, in no case are the various procedures more important than in cystic fibrosis (CF). CF is the most common life limiting genetic disease in Caucasians. The gene mutations commonly seen in CF are responsible for excessive chloride and sodium in epithelial cell secretions. This becomes problematic in the mucus-producing cells in the lungs because mucus becomes very thick and tenacious and cannot be easily cleared from the airways. This mucus accumulation leads to colonization and ultimate infection by various bacteria. The very nature of the pathological process leading to the tenacious and voluminous bronchial secretions inherent in CF demands the use of airway clearance techniques on a regular, on-going basis. More than two hundred fifty published articles and abstracts have described the effects of individual techniques and more recent studies have attempted to examine the differences between and among those techniques. It can be said without disagreement that the vast majority of airway clearance literature and research has focused upon patients with CF.

Emergence/Development of High Frequency Chest Wall Oscillation

During the past 10-15 years, there has been a marked increase in clinical popularity in the United States of an airway clearance device that produces high frequency chest wall oscillation (HFCWO), also called high frequency chest compression (HFCC) and high frequency chest wall compression (HFCWC). HFCWO has been shown to be effective^{6,7,8,9}, safe^{10,11}, and, very importantly, cost effective.^{12,13} Furthermore, HFCWO has increased airway clearance treatment adherence (typically very low), acceptance, and the quality of life for individuals and their families who use the device regularly.^{14,15} HFCWO is different than traditional chest physical therapy that includes manual percussion, or "clapping" therapy, which was the standard method of airway clearance in the past. HFCWO utilizes an air pulse generator to deliver air pulses through a flexible hose to an inflatable vest worn by the patient. Once the vest is inflated, the pulses repeatedly compress and release the chest wall. Each cycle begins with an air pulse that inflates the vest and causes compression of the chest wall. This compression creates a burst of air through the patient's airways that results in a brief cough-like response. At least one researcher has referred to this air movement as a "staccato cough". These rapidly recurring bursts of air, or staccato coughs, provide a shear force that cleaves the secretions from the walls of the airways. In addition to the shear forces, the air bursts reduce the viscosity of the secretions and move the secretions upward where they can be coughed or suctioned out. All lobes of the lungs are treated at the same time and the patient can sit upright throughout the entire treatment without having to assume the 10-12 different positions required for traditional postural drainage with percussion and vibration (PDPV).¹⁶ A HFCWO treatment typically requires 10 to 30 minutes, depending on the physician's prescription. The air pulses are delivered at a frequency of between 5 and 20 hertz, although frequencies around 13 hertz appear to provide the best results for secretion clearance.¹⁷

HFCWO provides several physiological mechanisms by which secretions in the lower respiratory tract are both loosened from the airway wall and moved proximally in the respiratory tree. The four prominent mechanisms are:

1) reduction in physical properties of mucus viscoelasticity and spinnability

Tomkiewicz et al were able to demonstrate an in vitro reduction in both spinnability of mucus and its viscoelasticity properties. That is, the mucus material became more fluid, and more easily cleared from the airway. The authors postulated that oscillating air flow as produced by HFCWO acts as a physical "mucolytic" agent that augments the cough clearability of the mucus.¹⁸

2) shearing effects upon respiratory mucus

Chang and colleagues developed a model to examine mucus transport produced by non-symmetrical oscillatory airflow as seen in HFCWO. Their results showed increased tracheal transport of mucus and related this transport to shearing forces produced at the air-mucus interface.¹⁹

3) cephalad bias in flow during HFCWO

King et al found that enhancement of tracheal mucus clearance in the cephalad direction (towards the head) was most pronounced with HFCWO in the range of 11 to 15 Hz, reaching a peak value of 340% of control at 13 Hz.¹⁴

4) a "staccato cough" mechanism propelling mucus proximally within the respiratory tract.

Warwick reported that the volume of air expelled from the lungs during the compression phase of HFCWO was much greater than with active forced expiration alone. Warwick called this effect a "staccato cough" and noted that this high level of expiratory volume and the associated high flows can be sustained without effort or fatigue on the part of the patient.²⁰

High Frequency Chest Wall Oscillation for Individuals with Neuromuscular Disease

The technique was initially developed for patients with cystic fibrosis, but over the past 5 years HFCWO has become an increasingly popular airway clearance technique for individuals not only with pulmonary diseases, but with respiratory consequences of many neuromuscular and neurological disorders as well. It is primarily this group of patients about whom this position paper is directed.

It is our claim that HFCWO is an outstanding airway clearance modality for individuals with neuromuscular diseases and should be recognized for coverage by insurance carriers. While not respiratory diseases themselves, the symptoms associated with these

many disparate conditions commonly result in major respiratory impairment and infection, often leading to respiratory failure and hastening the death of patients so afflicted. This respiratory impairment is often precipitated by inadequate clearance of secretions due to muscular weakness and inability to cough. Accumulated secretions disrupt the relative homeostasis that supports pulmonary defense mechanisms. A major issue regards harmful material in these accumulated secretions. This material may include micro-organisms, environmental substances, debris from excessive saliva, and others. This deleterious material stimulates the liberation of additional respiratory mucus, dysfunction in ciliary function, and the liberation of both primary and secondary inflammatory mediators.²¹ The net effect of this continuing series of events is to render the respiratory tree susceptible to on-going inflammation, periodic infection, and mechanical obstruction secondary to secretions and other inflammatory debris. In addition to these several concerns, there is evidence that chronic respiratory infections predispose strongly to diaphragmatic impairment.^{22,23} Divangahi et al concluded that sustained lung infection with *P. aeruginosa* in rats induces preferential weakness of the diaphragm. Therefore, the continuing presence of secretions and inflammatory material may lead to further impairment in respiratory function by virtue of diaphragmatic dysfunction. This vicious cycle of secretions with micro-organisms → inflammatory mediators → production of more secretions → infection → interference with diaphragmatic function is a cycle likely repeated in many neuromuscular and neurological diseases.

Among these disorders for which HFCWO can provide significant assistance are progressive myopathies such as Duchenne muscular dystrophy, spinal muscular atrophies, amyotrophic lateral sclerosis (ALS), cerebral palsy, infectious polyneuropathy, spinal cord injury, and other less common diseases of a similar nature. In addition, HFCWO is useful for individuals with other disorders that either acutely or chronically impair patients' ability to clear their airways by coughing.

Insurance Coverage for HFCWO

Some insurers indicate that traditional gravity-assisted PDPV followed by coughing or endotracheal aspiration via suction catheter provides adequate airway clearance for all. This fails to reflect contemporary practice and current expert opinion. Prior to the development of commercially available HFCWO, most airway clearance was comprised of traditional patient positioning for PDPV followed by deep breathing techniques and active coughing, suctioning, or huff coughing to raise and remove the sputum. This approach was effective for individuals with airway clearance encumbrance associated with pulmonary disease such as CF, COPD, and bronchiectasis. However, respiratory insufficiency secondary to neuromuscular disorders made these older airway clearance procedures much more difficult to provide. When applied to patients with neuromuscular disorders, the older or more traditional techniques:

- 1) are arduous and extremely fatiguing for the patient who must move into many different positions to assure drainage of secretions in all appropriate lung areas,

- 2) require a trained, skillful and committed health care professional or caregiver at home to administer,
- 3) are very expensive when administered by a professional therapist,
- 4) are very time consuming (up to one hour 2 or 3 times daily), and
- 5) pose the potential for adverse events such as hypoxemia^{24,25}, hemoptysis²⁶, and aspiration.

HFCWO presents none of these concerns.

Given the untoward consequences noted above with traditional airway clearance therapy, other approaches were developed in the past 20-25 years. Among these newer approaches, HFCWO remains the singular technique that does not involve a specific coordinated breathing technique which would likely prove difficult, if not impossible, for an individual with neuromuscular disease and associated respiratory muscle weakness or dysfunction. In addition, HFCWO can be easily carried out while a patient receives either invasive or non-invasive mechanical ventilation. These two issues of 1) difficulty coordinating respiratory efforts, and 2) the need for mechanical ventilation, mitigates strongly for airway clearance via HFCWO in patients with severe neuromuscular disorders.

CF is a discreet and clearly identifiable condition with its own ICD-9-CM code making identification uncomplicated and likewise making its own case for specific interventions, including airway clearance. Unfortunately this is not the case for individuals with significant respiratory dysfunction secondary to neuromuscular or neurological disease. Although the ICD-9-CM codes exist for these diseases, none of the diseases involve treatment that focuses initially on the respiratory complications. Nonetheless, these patients, just as patients with CF, have vital needs for airway clearance, albeit later in the course of the disease process. The diagnosis of a disease such as Duchenne muscular dystrophy, for example, is commonly made during early childhood. Fortunately for the child, the respiratory complications of the disease process are not likely to be experienced for a decade or more following diagnosis. As a result, decisions regarding insurance coverage and reimbursement that are typically based upon diagnostic codes do not take fully into account the changing needs of the patient, particularly as regards progressive neuromuscular disorders and the associated and *predictable* respiratory complications. When deciding upon airway clearance plans for individuals with neuromuscular disorders insurance coverage and reimbursement must be considered in a symptom-based approach rather than a diagnosis-based approach. For example, patients with amyotrophic lateral sclerosis are able to evacuate secretions early in the disease course, but often die from pulmonary infection as a complication of progressive respiratory muscle weakness and eventual respiratory failure.²⁷ Therefore, decisions by insurance carriers must consider not merely the diagnostic code, but changes during the progression of that primary diagnosis, the increasing severity of respiratory symptoms, and the potential for severe and often fatal respiratory complications, much of which follows inadequate control of respiratory secretions and debris.

Summary

HFCWO is an accepted and commonly reimbursed mode of airway clearance in the United States, particularly for children and adults with cystic fibrosis. Its mechanisms of action, efficacy, acceptance, and safety have been demonstrated and it has become a regularly prescribed and used modality for care of individuals with CF. There is good evidence that HFCWO resulted in clearance of greater volumes of sputum than traditional therapy, and a higher rate of successful weaning from the ventilator as well²⁸. In addition to the reduced cost associated with ease of self-treatment or family treatment, the weaning from mechanical ventilation poses both medical and financial benefits that accrue from HFCWO. Respiratory needs of the patient with progressive neuromuscular and neurological disorders are very similar to those with CF, albeit later in the course of the disease progression. As respiratory symptoms increase and neuromuscular function decreases, the symptoms must drive the decisions for reimbursement and coverage. We believe this position paper makes a strong argument for inclusion of HFCWO in the benefits for patients with these devastating diseases and that this benefit should be included at the early signs of secretion retention. By doing so, respiratory function and quality of life will be maintained for a longer period of time and hospitalizations will be decreased.

The Author

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For Mr. Tecklin's publication on neuromuscular patients and HFCWO, see Tecklin, J. High Frequency Chest Wall Oscillation for Individuals With Chronic Neuromuscular Weakness. *Respiratory Therapy* 2005 Dec/Jan; 1(1): 28-33.

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