HFCWO Therapy: A Change in Plan

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The adoption of high frequency chest wall oscillation (HFCWO) or vest therapy has changed rapidly in recent years. Usage for several traditional disease states has remained stable during the last six years, while several more have experienced remarkable growth. It should surprise no one that these growth patterns were disrupted by the emergence of the COVID-19 pandemic. While the number of new HFCWO patients suffered a steep decline in 2020, a few non-traditional diagnoses, chronic obstructive pulmonary disease (COPD) and chronic bronchitis, experienced strong growth. Many of these patients received their devices under regulatory flexibilities put in place by The Centers for Medicare and Medicaid Services (CMS) during the public health emergency (PHE). These flexibilities allowed for CMS coverage of respiratory devices, such as HFCWO, based on the physicians' determination of medical need of the respiratory device for their patient.[3,6] Our preliminary examination of outcomes for this group shows a 70% reduction in hospitalizations compared to the prior year, while self-reported ability to clear pulmonary secretions improved 51%.[1]

Key Points

- HFCWO usage patterns have changed in recent years.
- Originally used for cystic fibrosis and neuromuscular disease, this therapy has seen rapid adoption for non-CF bronchiectasis since 2015.
- COVID-19 has drastically changed these practice patterns in a single year.
- Flexibility put in place by CMS has allowed consideration of HFCWO therapy for respiratory patients who might not otherwise have received it.
- Self-reported outcomes from these patients show a robust improvement in hospitalization and the ability to clear mucus since initiating HFCWO therapy.

High frequency chest wall oscillation, also known as vest therapy, is indicated for respiratory patients who require airway clearance. Such patients often experience accumulation of secretions in the bronchi and small airways that may limit gas exchange in the lungs. Inadequately cleared secretions can become a culture medium for pathogens, leading to serious complications including degradation of lung function[2] and increased lung infections.[2,3] By providing periodic compressive pulses to the chest wall, the device transmits therapeutic vibrations to pulmonary airways; these vibrations thin and loosen the secretions, driving them upward to the mouth where they can be expectorated.[4] Acute illness and a progressive decline in lung function can occur when the normal mucus-clearing function is impaired or disrupted on a chronic basis.[5] Secretions that are not cleared can promote chronic inflammation, repeated infections, irreversible lung damage and impaired respiratory function.[6,7] Conditions that result in chronic mucus hypersecretion are considered candidates for airway clearance therapy, including HFCWO. These therapies are intended for patients who are unable to clear excess secretions without external manipulation or therapeutic intervention, and the range of such conditions is wide and often overlapping.

Since its invention almost 30 years ago, prescribing patterns for HFCWO have evolved, driven by changing medical practice and availability of new evidence. The number of prescriptions for many of its customary diagnoses — cystic fibrosis (CF) and neuromuscular disorders — has remained largely unchanged, mostly because patients with these diseases are readily identified and prevalence is small to begin with. Another diagnosis, non-CF bronchiectasis (hereafter referred to as "bronchiectasis") experienced explosive growth as it became clear that there was a large, underserved population of patients with this condition.[8] Comparatively, use of HFCWO for chronic obstructive pulmonary disease has grown more slowly, despite emerging evidence that many of these patients have excess sputum production and could also benefit from airway clearance therapy.[9,10]

HFCWO Adoption Grows

The Centers for Medicare and Medicaid Services (CMS) in the United States covers HFCWO for a number of diagnoses. These diagnoses may be categorized into four broad categories: *cystic fibrosis*, *neuromuscular disease*, *"other" respiratory illnesses*,

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This educational information offers general coverage, coding and payment information for procedures associated with use of HFCWO, which is indicated when external manipulation of the chest is the prescribed treatment to increase the clearance of mucus in patients with pulmonary disorders. This is not legal guidance, nor is it advice about how to code, complete, or submit any particular claim for payment. It is always the provider's responsibility to determine coverage and submit appropriate codes and charges for services rendered. This is based on the medical necessity of the services and supplies provided, the requirements of insurance carriers and any other third-party payers, and any local, state or federal laws that apply to the products and services rendered. Given the rapid and constant change in public and private reimbursement, we cannot guarantee the accuracy or timeliness of this information. Gary Hansen is the Director of Scientific Affairs, Respiratory Technologies, Inc. dba RespirTech, a Philips Company.

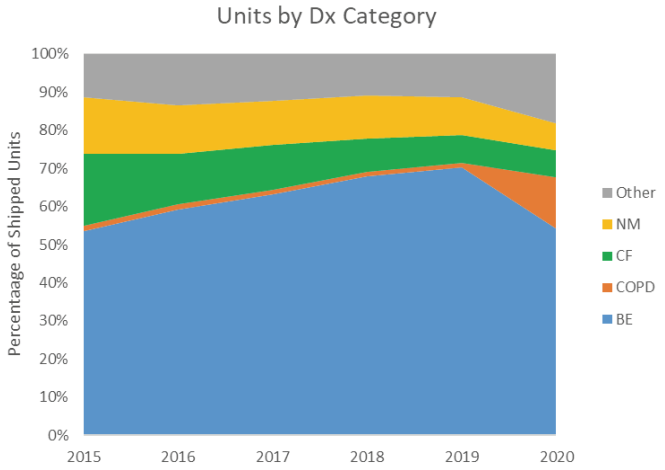

Figure 1. The proportion of HFCWO devices shipped to patients within five major diagnosis categories. "NM" is neuromuscular conditions, "CF" is cystic fibrosis, "COPD" is chronic obstructive pulmonary disease, "BE" is bronchiectasis. Data sourced from a proprietary business database of RespirTech, a Philips company.

and bronchiectasis. The proportionate share of these categories has changed considerably in the last six years, as shown by data from a proprietary customer database for one HFCWO manufacturer, RespirTech, a Philips company. (Figure 1)

HFCWO was originally designed to treat cystic fibrosis, a genetic disease that results in thickened pulmonary secretions that are difficult to mobilize without artificial methods of airway clearance. Numerous studies have shown HFCWO equivalent[11-18] or superior[19-23] to other airway clearance methods; accordingly, its use is now accepted as standard of care in the US.[24]

Within the neuromuscular category, HFCWO has long been used for patients who have an insufficient cough due to a variety of neurological and neuromuscular conditions.[25] (Figure 2) These disorders often result in respiratory muscle disability, making patients more susceptible to pneumonia and infection due to the inability to clear accumulated secretions through coughing.[26] Studies with these patients have found that HFCWO therapy can result in reduced hospital days,[27] a reduction in pneumonias,[28] and an overall reduction in healthcare utilization and costs.[29]

The "other" category contains a large number of uncommon respiratory diseases unrelated to the categories listed above. The RespirTech database shows that no single condition predominates the mix; unfortunately, there is little evidence regarding HFCWO use in this area, largely because they are low incidence conditions or else present other difficulties for doing clinical studies.

Among all diagnoses, bronchiectasis, has been the largest contributor to HFCWO adoption in recent years. This pulmonary disorder is characterized pathologically by permanent bronchial dilatation and severe bronchial inflammation. The clinical picture may include chronic productive cough, excessive sputum production, and recurrent infectious exacerbations. Once thought to be an orphan disease,[30] research has shown that a large population of undiagnosed and untreated individuals exists with this condition.[8] Further research has highlighted the value of HFCWO therapy in addressing the airway clearance needs for these patients.[31,32] Increasing awareness of the importance of recognizing and treating bronchiectasis has driven the adoption of international guidelines, which include recommendations for airway clearance.[33-35]

The results in this paper are from a single company, but nonetheless reflect a revealing snapshot of changes in medical practice as seen in the adoption of HFCWO for various diagnoses. Within this data set, distinct trends may be observed. Significantly, Figure 1 shows the impressive growth of bronchiectasis relative to other disease states. It may appear that the CF and neuromuscular categories have declined, but actual numbers have remained largely unchanged since 2015, probably due to low incidence rates and a relatively few undiagnosed patients with these conditions. In contrast, the "other" category has experienced a modest but steady annual growth rate of about 18% in the years before COVID-19, 2015-2019. The true driver of HFCWO has been the bronchiectasis category (J47.0, J47.1, J47.9), with an annual growth rate of 26% during the same period. This remarkable increase is attributable to the factors mentioned previously: more clinical evidence documenting the need for airway clearance therapy, more awareness of the disease, a large reservoir of undiagnosed patients, and a growing number of physicians who focus on it. The last issue we have not discussed is COVID-19, which of course has had a major impact on who has received HFCWO therapy in the year 2020.

COVID Intervenes

Since the recognition of the COVID-19 virus in late 2019, and its subsequent emergence into a worldwide pandemic, the lives of millions have been upended; this inevitably affected medical practice in many ways. Initial reports suggested that HFCWO therapy could have a role in addressing airway clearance needs of COVID-19 patients. An estimated 34% of hospitalized COVID-19 patients have excess sputum production.[36] In practice, HFCWO use for the COVID-19 diagnosis has comprised only a tiny fraction of all HFCWO patients in 2020 (about 0.2%).

Nonetheless, COVID-19 has radically changed HFCWO prescribing patterns in 2020, driving bronchiectasis numbers down, but COPD numbers up. This is explainable, at least in part, by the temporary changes put in place by CMS in response to the PHE. These provided greater flexibility for physicians to determine the medical need for respiratory devices, such as HFCWO therapy for their patients who might not otherwise

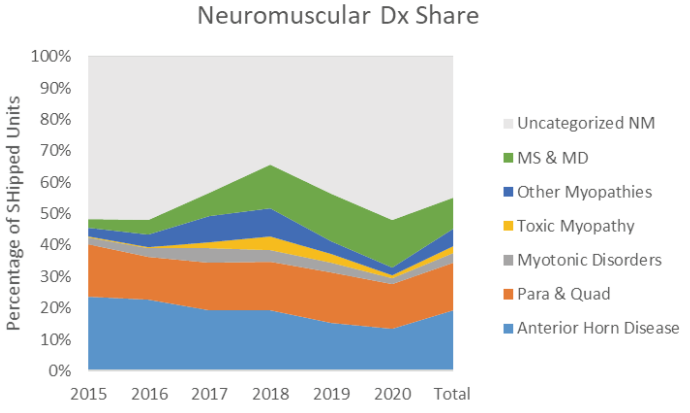

Figure 2. The proportion of HFCWO devices shipped to patients within the Neuromuscular category, with leading diagnoses called out separately. "MS" is multiple sclerosis, "MD" is muscular dystrophy, "Para" is paraplegia, "Quad" is quadriplegia, "anterior horn disease" includes amyotrophic lateral sclerosis. Data sourced from a proprietary business database of RespirTech, a Philips company.

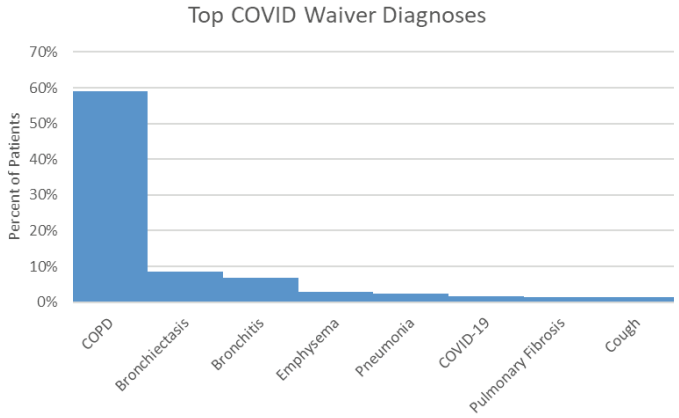

Figure 3. The proportion of various diagnoses for patients receiving HFCWO therapy under the COVID waiver. The top 8 diagnoses make up almost all of such patients. Data sourced from a proprietary business database of RespirTech, a Philips company.

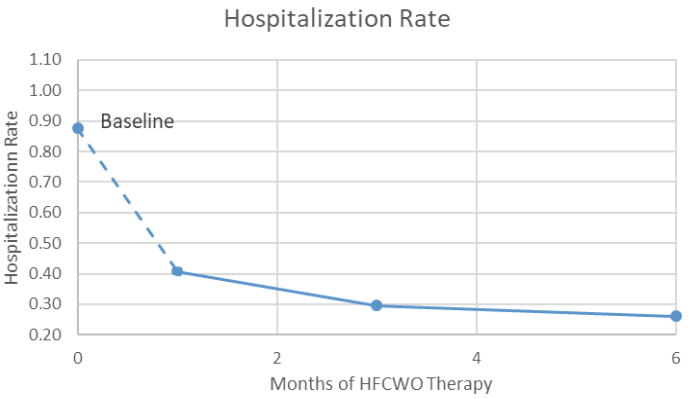

Figure 4. The reduction of annualized hospitalization rate for COVID waiver patients initiating HFCWO therapy. The baseline value is the hospitalization rate for the prior 12-month period. Data sourced from RespirTech Outcomes Registry.

qualify under CMS' medical polices for such devices [36] (referred to as "COVID waiver" in this paper). The intent was to make access to therapy less onerous during a time when clinic access is extraordinarily difficult. At the time of this writing (February 2021), the temporary changes are set to last until the PHE expires on April 20, 2021, but the PHE may be extended.[37]

Significant changes in prescribing may be seen for patients who have a preexisting respiratory disease. Figure 1 shows a steep drop in bronchiectasis prescriptions, perhaps reflecting reluctance on the part of physicians to subject patients to a High Resolution CT scan, which is normally required for a definitive diagnosis of bronchiectasis. In addition, concerns about visiting a clinic may have inhibited a number of patients from seeking medical assistance that is not immediately urgent. Many cases of bronchiectasis in the U.S. are found among patients with already-diagnosed chronic obstructive pulmonary disease; under the COVID waiver, patients with airway clearance issues may receive HFCWO directly, without the need for an additional diagnostic procedure. It seems clear that some patients who might have otherwise received a diagnosis of bronchiectasis found coverage in 2020 under the diagnosis of COPD. In fact, we do see a large increase in COPD diagnoses in 2020, an unknown number of which might also have bronchiectasis. We will now turn to the question of whether patients from this expanded population will actually benefit from HFCWO therapy.

Outcomes for COVID Waiver Patients

While the pandemic is certainly unwelcome, it does create a unique opportunity to evaluate the outcomes of HFCWO in otherwise non-covered patients. By providing vest therapy to a large number of new patients with respiratory illness, it is possible to track their outcomes and demonstrate that this form of therapy provides positive patient-reported benefits to otherwise non-covered patients. The RespirTech Outcomes Registry has followed COVID waiver patients since the beginning of the pandemic, finding among them a large number of patients with respiratory diseases, including COPD, that are not typically covered under CMS guidelines.

In fact, COPD makes up the largest proportion of diagnoses covered under the COVID waiver (Figure 3). A few bronchiectasis patients may be seen here, but the rest comprise a number of diagnoses that are not commonly covered: chronic bronchitis, emphysema, pneumonia, pulmonary fibrosis, and simple cough. This situation creates the unusual opportunity to assess the effectiveness of HFCWO therapy for this population. Two groups, in particular, experienced substantial growth in 2020: during that year, the number of chronic bronchitis prescriptions grew by 6.6 times, and COPD prescriptions grew by 9.9 times, compared to average of the prior five years.

There is reason to believe that vest therapy would be effective for these groups, particularly COPD patients who demonstrate a need for airway clearance therapy. The use of HFCWO for COPD has been the topic of some research.[38-40] A 2011 study compared the use of HFCWO to conventional treatment for patients with COPD.[41] The results showed the vest therapy device was well tolerated with good reported compliance, reduced symptoms and improved quality of life. More recently, results from RespirTech's registry of self-reported outcomes data found 54.4% reduction in the annualized hospitalization rate for respiratory causes, and a 51.9% increase in patients with favorable rating for "ability to clear lungs".[9] This last study was limited to 219 patients, while new patients covered by the COVID waiver represent the chance to greatly expand this patient count.

The RespirTech Outcomes Registry has been described in detail elsewhere,[32] but briefly it consists of self-reported outcomes by patients in certain diagnostic categories: originally bronchiectasis, but since enlarged to include COPD, Veterans Administration (VA) patients, and in 2020, COVID waiver. Once a new patient receives and is trained on their HFCWO device, they are enrolled in RespirTech's Outcomes Registry. At periodic intervals for the subsequent two years, they receive a phone-based survey asking about their hospitalization, antibiotic use, and several quality of life questions. Results are then compared to the prior 12-month period (hospitalization) or to the patient responses when they first receive the device (all other questions). The data shown in Figure 4 represent all COVID waiver patients from February through December 2020 (N=812, mean age 72.8 ±10.3).[1] After six months of HFCWO therapy, the hospitalization rate dropped by 70% (Figure 4), while the proportion those reporting their "ability to clear lungs" as good-excellent improved 51% and those reporting their "overall respiratory health" as good-excellent improved 41%. Finally, a point estimate of antibiotic use dropped 15%.

Conclusion

It is clear that HFCWO usage patterns have changed in recent years. No longer just for cystic fibrosis and neuromuscular disease, the field has seen the rapid adoption of vest therapy for non-CF bronchiectasis, with a number of other specific disease states growing at a more modest rate. The emergence of COVID-19 has changed these practice patterns in a single year, with the COVID waiver allowing physicians the flexibility to determine the medical need for respiratory devices like HFCWO, resulting in patients who might not otherwise be considered for HFCWO being evaluated and prescribed therapy. Our data shows that the majority of these patients had diagnoses that are not normally covered by CMS, primarily COPD. While past evidence suggests that HFCWO is beneficial for symptomatic COPD patients, the preliminary analysis of our outcomes data for COVID waiver patients implies a robust response to vest therapy.

References

1 Methodology: Phone surveys at regular intervals with COVID waiver patients using the InCourage system. Data collection began in February 2020. As of 12/31/20, 752 patients completed the baseline survey; 329 patients in 1-month cohort; 179 in 3-month cohort; 46 in 12-month cohort. The COVID waiver outcomes registry consists of 812 patient to date.

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