



Is chest physical therapy still the gold standard of airway clearance for cystic fibrosis?

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Summary

Is chest physical therapy still the gold standard of airway clearance for cystic fibrosis? This question is no longer even being asked as other airways clearance methods have been “shown to be as effective as chest physical therapy.” Yet, after review of these studies a better question would be, “Has the Gold Standard become merely Gold Plated?” Why have the CFF Guidelines not been followed in the various studies of airway clearance?

The airway clearance studies reviewed here tend to use the recommended procedures of the device manufacturer. These recommended procedures are then compared to truncated or undefined chest physical therapy treatment. In the future, newer airway clearance techniques should be compared to the effectiveness of the gold standard of properly performed chest physical therapy. Otherwise the cystic fibrosis patient may be provided with ACT choices that provide them with less than optimal airway clearance. Without using the true gold standard of CPT in AWC studies there is little chance for airway clearance technique development, nor a chance for a more efficient manner with which to obtain gold standard effectiveness with newer devices and/or methods. To date new AWC methods and devices have too often been compared to marginalized CPT demonstrating themselves to be only as effective as about one half of a proper CPT treatment.

From the standpoint of a chest physical therapist with a 40-year career treating cystic fibrosis, it would be refreshing to read a study that utilizes the gold standard established many years ago by the Cystic Fibrosis Foundation.

Studies should compare new methods to high standards of care, not merely to a partial facsimile. And we must be careful not to trade implied convenience and/or independence for sub-standard care, for cystic fibrosis is indeed an inconvenient disease, and all airway clearance methods are inconvenient routines. But increased morbidity and mortality are the ultimate inconvenience. In our search for more efficient and effective airways clearance methods we should take care to keep our standards high. For how else can we answer the question, “What is the best ACT for this patient?”

Purpose

Comparative studies of airway clearance (AWC) methods have been inconclusive leading to the consensus that one treatment method is as good as the next. Shortcomings of the plethora of AWC studies are discussed in the “2014 Cochrane Review of Oscillating devices for airway clearance in people with cystic fibrosis.” Included in the shortcomings are the issues of short duration studies using small numbers of subjects and questionable outcome measures.

The Cochrane Review also describes the wide variety of treatments that may be termed chest physical therapy. We reviewed some of these comparative studies asking the question, “...as compared to what sort of chest physical therapy?”

In 2003 we reviewed oft cited AWC studies in an internal Chest Physical Therapy Services (Quincy, MA) paper. The review demonstrated a need to use a standard of chest physical therapy

(CPT) to which other airway clearance methods can be compared. What is termed chest physical therapy in the studies is quite varied.

AWC studies of the past might have obtained much different results had the actual “gold standard” of chest physical therapy been used. This gold standard is described in Guidelines for Segmental Bronchial Drainage (CFF Guidelines) adopted and published long ago by the Cystic Fibrosis Foundation (CFF). This gold standard is mentioned in some studies of AWC, yet the CFF Guidelines never seem to be used in those studies. Furthermore, it is important to consider that there is wide variation in treatment quality when family members are responsible for chest physical therapy treatments, including during studies.

Not even all therapists can perform the treatment well. CFF Guidelines have been followed by our physical therapists (since 1975). Only therapists trained in chest physical therapy (trained at their school, by a hospital, or by our staff) treat our patients. Each therapist is given the CFF Guidelines protocol and is expected to follow it for all treatments unless there is a documented medical rationale to deviate from it.

In future studies of CPT treatment quality could be more standardized if the chest physical therapy is provided by properly trained and practiced professional physical therapists. To be informative about a technique studies should use the highest quality of treatment available rather than a marginalized representation of the technique.

So what is this CPT “gold standard?” The “Gold Standard” for airway clearance in cystic fibrosis treatment had been chest physical therapy. This standard is well defined in the Cystic Fibrosis Foundation Guidelines for Segmental Bronchial Drainage (1986) and the CFF Consumer Fact Sheet - An Introduction to Chest Physical Therapy (1997). These guidelines call for twelve postural drainage positions. In each position the patient’s chest is treated with two to three minutes of vigorous manual percussion using cupped hands. Vigorousness (percussion force) is limited to patient tolerance. Following percussion, the patient is asked to take five deep inspirations and manual vibration is performed to the chest while the patient breathes out through pursed lips. After five vibrations have been performed, the patient is then asked to sit up and huff and/or cough to move and expectorate any available pulmonary secretions. Although the CFF Fact Sheet defines ten postural drainage positions, historically the number of “positions treated” with manual percussion and vibration has been twelve. The posterior segments of the upper lobes are treated separately as right side and left side, and we also have treated the posterior basal segments separately as right and left “positions” to bring the total to twelve. A very efficient chest physical therapy treatment takes a minimum of 36 minutes - twelve positions with 2 percussion minutes (24) plus one minute required for five vibrations and a cough (12) is 36 min. Additional coughing, percussion and positioning and patient resting will (and most frequently does) add time to the treatment. In the studies reviewed here treatment times are most often quite less than 36 minutes or are undefined.

With the proper use of this gold standard of chest physical therapy some postural drainage positions may be more productive of sputum than others. This varies from patient to patient and even from treatment to treatment. Any productive position can be done again and again until secretions are cleared. More percussion, more deep breathing, and more vibration can be used to optimize treatment for a particularly productive postural drainage position. Attempts to standardize airway

clearance treatments in comparison studies have not allowed this important aspect of chest physical therapy treatment to occur. With the omission of some of the postural drainage positions from a chest physical therapy treatment, it is obviously quite possible to miss a highly productive drainage position along with the chance to exploit it for improved bronchial clearing.

Such chest physical therapy treatment tailored to the individual patient is rarely (if ever) used in studies. Yet this is precisely the method a professional chest physical therapist should employ. If not, the effectiveness of the chest physical therapy treatment may certainly be compromised.

During postural drainage positioning the upper most portion of the lung is said to be best ventilated with air, while the lower most portion of the lung is best perfused with blood. Eliminating postural drainage from airways clearance methods eliminates any possible advantages of these gravitational effects on increased segmental ventilation in addition to the more obvious effect of segmental mucus drainage.

Some studies we review here omit the technique of manual vibration. Yet there are purposes for this technique in chest physical therapy treatment. A deep inspiration attempts to ventilate the airways and lungs which is an obvious goal of airway clearance treatment. Improved ventilation improves mucus mobility and enhances clearance during manual vibration upon expiration. The manual vibrations can decrease mucus viscosity and assist mucus movement for subsequent clearance during coughing. With some mucus cleared and improved ventilation obtained, the airways are better prepared for successful mucus clearance in the next postural drainage position. Proper manual vibration is an important part of a chest physical therapy treatment and should not be omitted during studies measuring chest physical therapy effectiveness.

Combined with postural drainage, manual percussion also often elicits a spontaneous cough that aids in clearing sputum during a chest physical therapy session. Spontaneous coughing is an important feature that may add to the effectiveness of chest physical therapy. Spontaneous coughing may or may not be elicited as frequently, or at all, with other forms of airway clearance that do not use postural drainage positioning. One study we reviewed attempted to standardize the number of coughs allowed during various treatment regimens. Studies that standardize coughing may diminish or lose any enhanced effectiveness resulting from the spontaneous coughing elicited by either chest physical therapy or the compared procedure.

The following studies conclude that an alternative airway clearance method is as effective as chest physical therapy. Yet our review indicates that the “gold standard” of chest physical therapy was often only dosed at about one half of what we have long considered to be a standard chest physical therapy treatment.

Rather than marginalize the chest physical therapy standard, perhaps it would be more informative for future studies to perform chest physical therapy to a high standard, the true gold standard. Then, if standardization needs to be undertaken, the new airway clearance method should be adapted to determine if it meets or exceeds this gold standard. The full effectiveness of chest physical therapy is lost if only half of the available postural drainage positions are used, if manual vibration is omitted, if coughing is limited, and/or if sputum producing postural drainage positions cannot be re-treated.

Prologue to Review

The following studies have often been referenced as evidence for the comparative effectiveness of chest physical therapy. Yet with each study we demonstrate that either an incomplete form of chest physical therapy treatment or an ill-defined chest physical therapy treatment was used that, as such, cannot be duplicated in future studies. In these studies, the chest physical therapy does not nearly represent the gold standard. Each study has a combination of the following limitations that call into question the conclusions drawn by the authors.

- The CPT protocol was not well defined and therefore cannot be duplicated
- The CPT did not use all postural drainage positions as defined by CFF Guidelines
- During CPT deep inspirations with manual vibration on expiration between positions was limited or omitted
- No allowance existed to re-treat high sputum producing postural drainage positions
- The effectiveness of spontaneous coughing during CPT was discounted

Review

Please note that in the following studies High Frequency Chest Compression (HFCC) evolved over time to be called High Frequency Chest Wall Oscillation (HWCWO) yet they are the same, and also known as a vest device.

In their 1990 paper “High-frequency Chest Compression System to Aid in Clearance of Mucus from the Lungs,” Hansen and Warwick describe in detail their new system for High Frequency Chest Compression. Their paper concludes with the statement,

“Preliminary observations have shown HFCC to be more effective than standard chest physical therapy, with a statistically significant increase in the clearance of mucus and evidence of improved pulmonary function.” This paper’s final statement is based upon

comparisons of five cystic fibrosis patients who received “...thirty sessions (of) HFCC at 12-16 Hz, and 30 sessions of standard chest physical therapy by a certified respiratory therapist...”

In this study there is no definition of “standard chest physical therapy” presented. There is no explanation of the chest physical therapy protocol. The authors attempt to standardize the two airway clearance protocols in that, “...times of day of the therapy sessions were matched and the total volume of mucus cleared during each session was recorded. All therapy sessions were of the same duration.” Yet, unfortunately we do not know what sort of chest physical therapy was utilized. What was the CPT used in this study?

In 1991 Warwick and Hansen describe using twelve postural drainage positions for an average of 23 months in their frequently cited study, “The Long Term Effect of High-Frequency Chest Compression Therapy on Pulmonary Complication of Cystic Fibrosis.” Their description of prescribed chest physical therapy in paragraph eight of their paper is, “12 twelve positions preceded by bronchodilator and

mucolytic aerosol, and followed by huffing and directed coughing after each of the 12 positions. This pre-HFCC therapy required 10 to 15 minutes of aerosols and 35 to 40 minutes for the manual chest physical therapy.” There is no mention of the amount or force of manual percussion and /or vibration, or the expertise of the care giver. We only know that “HFCC therapy was prescribed on a one-for-one replacement for prior manual chest physiotherapy.” We may assume that “prior manual physiotherapy” means percussion and/or vibration, yet we are given no guide as to how or what treatment techniques were or were not employed.

It is not until paragraph sixteen in the Discussion portion of the paper that we learn that the chest physical therapists were the patients’ parents. Nothing is mentioned regarding attempts to determine patient/parental training or proficiency. There are no techniques for measuring compliance with either airway clearance method. We do not know if complete or partial chest physical therapy treatments are omitted. Without any observation of parental treatment technique, it is impossible to know how vigorous or complete the treatment sessions were. In paragraph eighteen the authors note that there was a tendency toward less compliance with the chest physical therapy than with the HFCC and therefore the “study cannot distinguish improvement between more regular therapy and improvement due to a better way to provide therapy.” Yet the authors conclude that “...HFCC can replace manual chest physical therapy...” We would certainly add “...as performed by parents with an unknown level of training,” and, “...with unknown rates of compliance” to this conclusion. We are encouraged that a long-term study was attempted. Yet, from the text it is impossible to know if this study compared HFCC to the gold standard of chest physical therapy.

In 1993 Whitman et al published “Preliminary Evaluation of High-Frequency Chest Compression for Secretion Clearance in Mechanically Ventilated Patients.” This is a four-day cross over study of (non-cystic fibrosis) “...long-term mechanically ventilated patients who required Percussion and Postural Drainage therapy.” The chest physical therapy protocol consisted of, “Percussion applied for two minutes over each of 5 regions: anterior segments of both upper lobes, right-upper-lobe posterior segment, right-lower-lobe lateral segment, left-upper-lobe posterior segment, and left lower lobe lateral segment. Patients were positioned 15 degrees Trendelenburg for drainage of lower lobes.” In the HFCC protocol, “HFCC was administered at 8 Hz and 16Hz, each for five minutes, according to the manufacturer’s recommendations. Therapy was performed with patients sitting in the semi-Fowler’s position and proceeded from the lowest to the highest frequency. HFCC was applied during both inhalation and exhalation throughout the entire 10-minute therapy session.”

This study thus compared two forms of airway clearance that lasted only ten minutes per treatment session. Not surprisingly, the authors found that, “No significant difference in the wet weight of collected sputum was found between the two therapy techniques.” With so little airway clearance therapy being performed in either protocol the effectiveness of either airway clearance technique comes into question. It would have been interesting to compare this minimal amount of therapy to a control group of patients receiving no airways clearance therapy. The CPT in this study is quite sub-standard as only four upper lobe segments and only two lower lobe segments were treated. Positions for the right and left apical segments, the right middle lobe, the lingula of the left lung, the right and left anterior segments of the lower lobes and the right and left posterior segments of the lower lobes were all omitted from treatment. The authors conclude that, “...the results of our evaluation lead us to believe that HFCC is a viable alternative to P&PD for secretion clearance in chronically ventilated patients.” Our review indicates that this study shows a limited ten minutes of

HFCC to be as effective as a limited ten minutes of chest physical therapy. Yet the actual effectiveness of either protocol as compared to no treatment at all remains a serious unknown.

In 1994 Raanan Arens, et.al. published "Comparison of High Frequency Chest Wall Compression and Conventional Chest Physiotherapy in Hospitalized Patients with Cystic Fibrosis." In this 14 day study the treatment provided to the HFCC group is very well defined, with treatment periods of four to five minutes at each of the six various frequency settings. Then the patients performed three maximal inhalations with the HFCC device being activated during expiration. The patients were instructed to actively cough following each of these three expiratory maneuvers.

Unfortunately, the standard for CPT in this study is not the gold standard, and the protocol used is much less defined than the HFCC group. In the chest physical therapy group "Postural drainage was performed in six positions (four lying and two sitting), and percussion was administered for 4 min in every position." And while "Patients in the CPT group were treated for a period of 30 min, 3 times/d by a respiratory therapist using conventional methods of percussion and postural drainage," no mention of deep breathing, vibration or coughing is included in the chest physical therapy group as it was in the HFCC group. Yet, it is clearly explained that the HFCC group did perform expiratory maneuvers and coughing. The authors state that, "This study shows that HFCC and CPT have similar effects on clinical status, improvement of PFT, and sputum clearance during acute pulmonary exacerbation in CF patients." They conclude that, "...HFCC and CPT are equally safe and effective in the management of acute pulmonary exacerbations in CF patients." Yet, the chest physical therapy performed in this study omitted six postural drainage positions. Any possibility that one of those omitted positions or coughs may have produced increased sputum is lost. HFCC has been optimized in this study while CPT has been marginalized. HFCC was not compared to the gold standard.

In their 1995 study, "Short-Term Effects of Three Chest Physiotherapy Regimens in Patients Hospitalized for Pulmonary Exacerbations of Cystic Fibrosis: A Cross-Over Randomized Study" C Braggion, MD et al state: "We concluded that there were no differences in the short-term efficacy between the three CPT regimens on hospitalized patients with CF." The three regimens compared were HFCC, positive expiratory pressure (PEP) and chest physical therapy.

The gold standard for CPT is not used in the study. The Postural Drainage description utilizes only six postural drainage positions, and the positions varied from patient to patient "...based on the most recent chest radiography for each patient." If only generalized changes had occurred, "...positions were chosen that clear the anterior and posterior segments of both upper lobes, the right and left middle lobes, and the posterior basal segments of both lower lobes." This indicates that anterior and lateral segments of both lower lobes and apical segments of the upper lobes were omitted. The amount of percussion and vibration totals five minutes per position, but how much of each technique was utilized is vague. "During the 5-minute period in each different position the physiotherapist combined a regimen of deep breathing with vibrations during expiration, and relaxed breathing with manual percussion, using clapping with cupped hands, over the chosen areas." We do not know how much of the five minutes was spent doing manual percussion and how much was manual vibration. Nor do we know, even in relative terms, how vigorous the manual percussion and vibration was performed. During each of the five-minute HFCC and PEP treatment periods we understand, and we can duplicate the treatment procedure. Yet we can only guess at what was being done during the chest physical therapy treatment and cannot duplicate this study.

Table 1 in this study shows a difference in the wet and dry weight of sputum produced, showing that postural drainage (chest physical therapy) produced more sputum. Yet the authors standardize this result to the number of patient coughs, which therefore decreases the significance of the increased sputum produced. Table 2 shows that the PD (chest physical therapy) sessions elicited more coughs during treatment.

Our review finds that the results show that limited and poorly defined postural drainage with five minutes of percussion and vibration produced more coughing than HFCC and PEP, and also produced more sputum than HFCC and PEP. This fact is dismissed in the study and is lost by standardizing the number of coughs. In the real world of patients do not standardize their coughing. A method of airway clearance that elicits more coughing may very well clear more mucus from the airways. Yet the authors conclude that, "...no evidence of a greater short-term efficacy of one regimen compared to another was found." Our review of this study concludes, conversely, that using only half of the CPT gold standard elicited more coughing and more sputum than HFCC or PEP.

In 1996 Kluft, et al published "A Comparison of Bronchial Drainage Treatments in Cystic Fibrosis." In this four-day cross over study six High Frequency Chest Wall Oscillation (HFCWO) frequencies were used for five minutes each. After each five-minute period the patient was instructed to perform an inspiration to total lung capacity at which point the HFCWO device was again activated while the patient "huffed" (forced exhalation). There is no mention as to how many huffs were performed. Active coughing to clear secretions followed huffing. During the five-minute HFCWO periods the patient inhaled nebulized saline. Five minutes of HFCWO at six different frequencies is thirty minutes of HFCWO. In their abstract the authors state, "...treatment frequency and the length of treatment were the same for both techniques."

The HFCWO protocol was compared to a chest physical therapy/postural drainage protocol (CPT/PD) that consisted of "...chest percussion with postural drainage of five sites for 2-3 min/position. Vibration of the chest wall is created by the therapist following percussion of each site, and a forced cough is then encouraged. The five positions are rotated during each of the three therapy sessions throughout the day. In this way, all lobes are percussed in a 24-hour period."

This description of CPT/PD indicates that CPT was performed for 10 to 15 minutes three times per day and only five postural drainage positions were used. We do not know how many forced exhalations with vibration were performed following chest percussion. The rotation of postural drainage positions is unclear. How many total positions were used and what were they? The gold standard CPT treatment was not used in this study. Yet authors state that, "The data from this study indicate that mucus clearance by HFCWO is an effective alternative to manually performed CPT/PD."

This study suggests that HFCWO is at least as effective as manual CPT/PD in clearing secretions from the airways in patients with cystic fibrosis." Our review finds that proper chest physical therapy treatment was lacking in many respects, and HFCWO was advantaged by inhalation of normal saline, creating serious flaws in the results and conclusions of this study.

In 1998 Scherer et al published "Effect of High-Frequency Oral Airway and Chest Wall Oscillation and Conventional Chest Physical Therapy on Expectoration in Patients with Stable Cystic Fibrosis." Five treatment regimens were compared. Two regimens used high frequency airway oscillation, two

used high frequency chest wall compression, and the fifth was described as, “conventional chest physical therapy (CPT).” In the abstract the authors state that, “As measured by sputum wet weight, all oscillatory devices tended to be less effective than CPT. As measured by dry weight, oral airway oscillation at 8 Hz with an I:E ratio of 9:1 and CPT tended to be more effective than the other treatment modalities.” The authors provided a detailed description of the four high frequency oscillation treatment regimens, providing information regarding patient positioning, oscillation frequencies, inspiratory/expiratory ratios and supportive equipment. They derived “an empiric oscillatory clearance index (OCI)...” and, “Based on the theoretical index, preliminary experiments were conducted to find out optimal settings for the oral airway and the chest wall oscillator to transport mucus in a cephalad direction.”

Unfortunately, the description of chest physical therapy was merely that, “CPT consisted of postural drainage (head-down tilt 30 degrees), clapping, external vibration with a standard electrical chest wall percussor (frequency 40 Hz) and encouraged coughing.” There is no other description of positioning, or how long percussion and vibration were performed per position, or how vigorous the (clapping) percussion was performed. We do know that for each session of all the protocols, the treatment lasted twenty minutes. This certainly, then, is not representative of gold standard chest physical therapy, which requires a bare minimum of 36 minutes.

Though the authors found that “No treatment proved to be significantly more effective than the others,” we note that in Figure 1 the chest physical therapy session (limited as it was) did produce more wet weight and more dry weight sputum than the other treatment regimens. And while pulmonary function changes in all regimens were not significant for this short-term study, we again note in Figure 2 that both FVC and FEV1 improved more in the chest physical therapy group than in the other groups. The authors state that, “Our results are consistent with findings of previous experiments, which showed that high-frequency chest wall oscillation is at least as effective as CPT in patients with cystic fibrosis who are in stable condition or suffer from acute exacerbation.” We must wonder what the results might have been had the gold standard of chest physical therapy been allowed to participate in this study, rather than the limited version of CPT that was performed.

In January of 2003 Varekojis et al published “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.” The abstract of this short-term study states, “The mean wet sputum weights differed significantly. Wet sputum weights from IPV were significantly greater than those from HFCWC. The mean dry sputum weights were not significantly different.” Table 2 in their study shows that the sputum wet weight from postural drainage and percussion fell between IPV and HFCWC. The authors conclude that,

“...the amount of sputum produced using HFCWC and IPV devices appears to be equivalent to the amount produced by vigorous professional PD&P.” In this comparison, “All treatments lasted 30 minutes, consisting of 24 minutes of therapy and 6 minutes of directed coughing.”

The chest physical therapy protocol called for 12 postural drainage positions with two minutes of percussion in each position. Unfortunately, there was no mention of deep inspirations with vibration on expiration. Furthermore, it seems from the chest physical therapy description that percussion was performed in four postural positions without any deep breathing or vibration or coughing between

positions, and then after two minutes of percussion in each of four position there was two minutes of directed coughing. Next, percussion in another four positions was completed and followed by another two-minute period of directed coughing. Then the final four positions were completed, followed by two minutes of directed coughing. This routine was used to standardize chest physical therapy to the other two protocols. Those used 8 minutes of treatment at four different frequencies, with each eight-minute treatment followed by 2 minutes of directed coughing.

While it is encouraging to see that an entire compliment of twelve postural drainage positions were used for CPT in this study, this is not the gold standard method, which allows for ventilation and vibration following each position. Chest physical therapy effectiveness is also limited in that a particular position could not be treated longer if it produced more sputum than other positions, which is one great advantage to chest physical therapy.

In the standardization process it seems that chest physical therapy performance is marginalized to accommodate the other two protocols. In addition, the IPV group inhaled normal saline during the IVP treatment session, while the HFCWC and chest physical therapy groups were not afforded that protocol. This certainly may account for the higher sputum weights from IVP. The authors do cite this and other limitations including the use of sputum weight as an outcome measure. They share our concern that, "...it has not been clearly established that short-term increases in clearance preserve pulmonary function, decrease morbidity, or improve quality of life."

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