

NINETY-DAY ASSESSMENT OF THE EFFECT OF HIGH-FREQUENCY CHEST WALL OSCILLATION (HFCWO) ON EXERCISE TOLERANCE AND QUALITY OF LIFE OF PATIENTS WITH CHRONIC OBSTRUCTIVE PULMONARY DISEASE

Mark J. Rumbak, M.D., F.C.C.P.¹, Victor L. Marchione, M.D., F.C.C.P.², Timothy C. Kennedy, M.D., F.C.C.P.³, and Mark W. Rolfe, M.D., F.C.C.P.¹
 University of South Florida, Tampa, FL¹; Institute for Better Breathing, Jersey City, NJ²; Colorado Pulmonary Associates, Denver, CO³

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INTRODUCTION

- COPD therapy, targeted at reducing symptoms and exacerbations and improving quality of life (QOL), remains sub-optimal despite pharmacological advances.
- Many patients with COPD have excess mucus production and retention, but airway clearance therapy is typically not a regular component of their care.
- Mucus hypersecretion and retention may adversely affect some patients with COPD to a greater degree than previously considered.
- High-frequency chest wall oscillation (HFCWO) has been widely used to clear excess sputum from patients with cystic fibrosis as well as other diseases and conditions associated with retained secretions.
- We postulated that patients with COPD who have evidence of retained secretions may also benefit from HFCWO.

OBJECTIVES

- To assess the effects of HFCWO provided by The Vest™ Airway Clearance System (Advanced Respiratory, f.k.a. American Biosystems, Inc., St. Paul, MN) on pulmonary function, symptoms, exercise tolerance, and QOL during a short-term trial period.
- To assess HFCWO treatment adherence and satisfaction of patients with COPD.

METHODS

- Patients with COPD > 40 years old, FEV₁ < 70%, evidence of retained secretions and dyspnea or decreased functional ability who provided informed consent were enrolled in a 90-day Vest trial.
- Baseline medical history, PFTs, 6-minute walk distance, dyspnea (Borg and baseline/transitional dyspnea), symptom and SF-36 QOL scores were determined.
- Patients received in-home training on The Vest™ and were instructed to do two 15-30 minute treatments daily.
- Treatment adherence and satisfaction was monitored during the 90-day period.
- After 90 days, study participants underwent re-evaluation of the outcomes taken at baseline. Each patient served as their own control.

STATISTICS

Data collected from the 3 study sites were entered and analyzed by the University of Minnesota Consulting Service.

- T-tests were used for continuous outcome variables to evaluate:
 - differences in mean values between two groups (2-sample T-test).
 - significant changes over time, baseline to 90-day (paired-sample T-test).
- Chi-square tests were used of categorical variables to evaluate significant associations between follow-up status and the categorical variable, level of sputum production, at baseline.
- Data expressed as mean ± SEM, * = statistical difference (p < 0.05), ** = high statistical difference (p < 0.001)

RESULTS

Baseline Characteristics

Characteristic	Mean ± S.D.
Age (years)	66.1 ± 10.0
Gender	50.6% female 49.4% male
Weight (lbs)	167.5 ± 39.7
Body Mass	26.4 ± 6.0
FEV ₁ % predicted (pre)	39.3 ± 13.7
FEV ₁ % predicted (post)	44.8 ± 16.0
FEF ₂₅₋₇₅ % predicted (pre)	19.9 ± 15.3
FEF ₂₅₋₇₅ % predicted (post)	25.7 ± 26.6
Smoking Hx (pack years)	58.3 ± 35.8
# ER visits/past year	1.9 ± 3.3
# hospitalizations/past year	0.4 ± 0.8

• **Patient Treatment Status at end of trial:** Of 85 study patients in the 90-day trial, 59 completed 90 days (69.4%); whereas 26 (30.6%) did not. Of the 59 that completed the 90-day trial, 21 (35.6%) discontinued therapy (DC group) after the trial; whereas, 38 (64.4%) were given a prescription (RX group) to continue therapy after the trial based on their positive treatment outcomes, satisfaction and adherence.

Outcomes after HFCWO therapy

Symptom Scores:

• Compared to baseline, all patients receiving 90 days of HFCWO therapy reported an overall improvement in symptoms (p < 0.0002). There was no significant difference between patients (DC vs RX).

Six-minute walk distance:

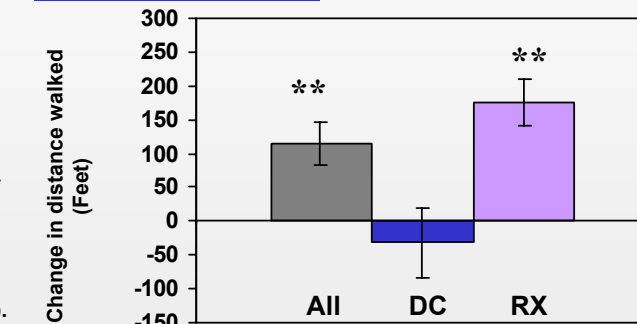


Fig. 1. Patients completing 90-days of HFCWO therapy exhibited a statistically significant improvement (p < 0.001) in the 6-min distance walked; however only the patient group selected to receive a Lifetime prescription (RX) reached both statistical and clinical significance (p < 0.001, 175 ft improvement). The RX group also had less change in perceived breathlessness upon exertion (mean difference in Borg score change at 90 day vs 0 day = -0.5 ± 0.2, p < 0.02). There were no significant differences in SaO₂ or heart rate changes. The group that discontinued (DC) therapy had no improvement in their 6-minute walk distance.

Pulmonary Function:

• There were no statistically significant differences in PFTs between baseline and 90-days, although trends toward improvements in FEV₁, FVC and FEF₂₅₋₇₅ after 90-days of therapy were seen (mean differences 2.8 ± 2.1, 2.7 ± 2.4, 2.6 ± 2.1, respectively).

Transitional Dyspnea Index:

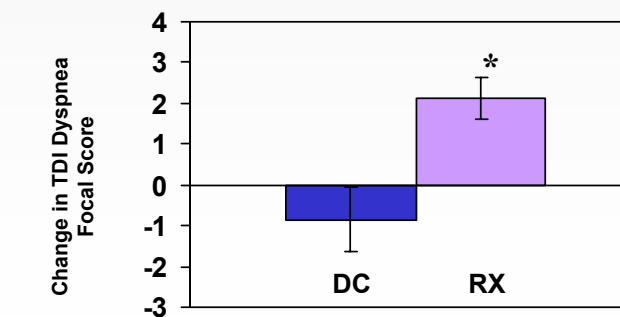


Fig. 2. There was a significant difference between the change in dyspnea in DC vs RX patients after 90 days of HFCWO.

QOL (SF-36):

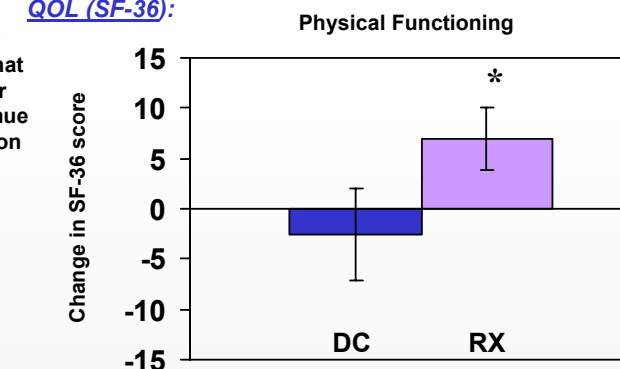


Fig. 3. There was a significant difference in the physical function domain for RX but not DC patients at 90 days compared to baseline.

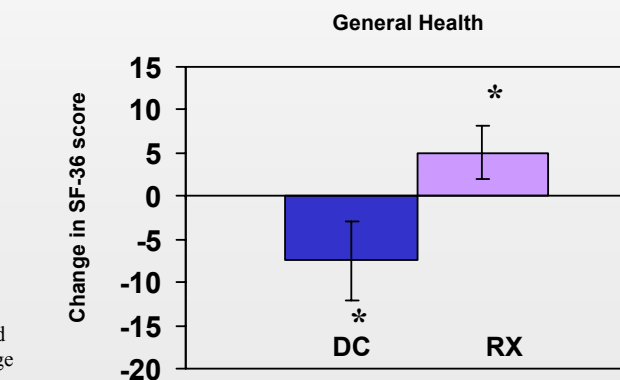


Fig. 4. There were significant differences in the general health domain for RX and DC patients at 90 days compared to baseline.

HFCWO Treatment Satisfaction:

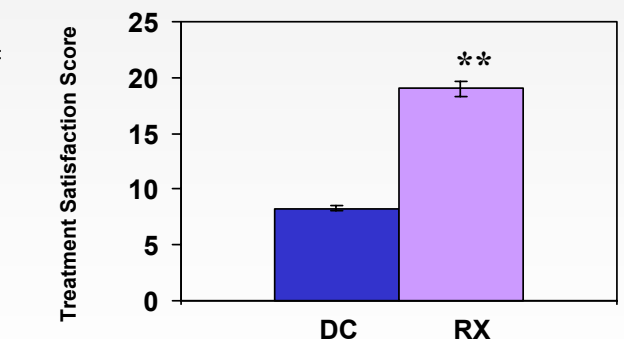


Fig. 5. There was a highly significant difference in treatment satisfaction between the two groups.

HFCWO Treatment Adherence:

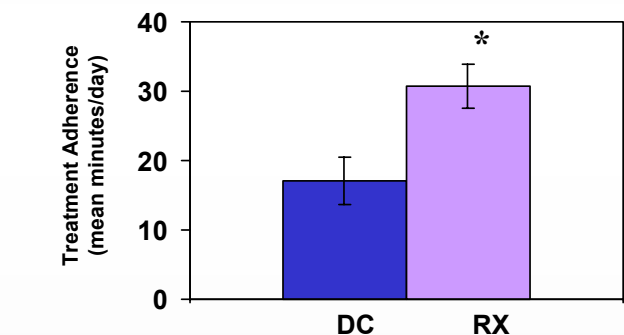


Fig. 6. There was a significant difference in treatment adherence between the two patient groups.

DISCUSSION

- Symptom, six-minute walk distance, dyspnea and QOL improvements may be seen in select patients with COPD who use HFCWO therapy.
- We postulate that clearing excess, retained secretions via HFCWO in these patients may reduce air trapping and facilitate improved exhalation. Further studies are needed to prove this hypothesis and to explore other possible mechanisms.
- Specific baseline characteristics that may help identify patients with COPD that are likely to benefit from HFCWO therapy have not been completely delineated, but further analysis is in progress.
- A trial period of HFCWO therapy can help identify those patients with COPD that are most likely to use and benefit from HFCWO therapy.

CLINICAL IMPLICATIONS

- Patients with COPD may improve their symptoms, function and QOL with regular airway clearance provided by HFCWO. A short-term therapy trial period is beneficial to determine which patients are most likely to adhere and benefit from this type of therapy.

Support: Advanced Respiratory, St. Paul, MN