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INTRODUCTION

High-frequency chest wall oscillation (HFCWO) is commonly used airway clearance technique in patients with cystic fibrosis (CF).

HFCWO is an inflatable vest that applies small volume expiratory pulses to the external chest wall, generating a high velocity expiratory airflow that is thought to mobilize secretions by the shear force created [Figure 1]. Despite this clinical rationale, the mode of action still remains unknown

A limitation in the use is the requirement for an AC power source. A mobile device that generates chest wall pressure and oscillating airflow comparable to AC powered devices has the potential to alleviate this challenge.

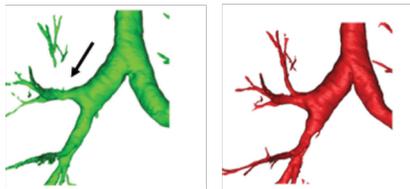


Figure 1: Change in airway patency by FRI before (green) and after (red) ACT¹

AIM

- to assess the mode of action of mobile HFCWO
- to evaluate the effectiveness of the mobile device (The Monarch® System) compared to standard HFCWO (The Vest® System) [Figure 2]



Figure 2: Mobile HFCWO (The Monarch® System) versus standard HFCWO (The Vest® System)

METHODS

The study was a randomized, open-label, crossover trial.

Inclusion criteria:

- age ≥ 15 years
- stable CF medications (prior 4 weeks)
- daily sputum production.

Exclusion criteria:

- FEV₁ % predicted < 30% or > 90%
- history of pneumothorax (past 6 months),
- hemoptysis requiring embolization (past 12 months),
- IV antibiotics in 4 weeks prior to visit
- exacerbation of allergic bronchopulmonary aspergillosis or anticipated hospitalization (next 3 weeks).

Airway Clearance Technique (ACT): HFVCO

Patients were randomized to mobile device or standard device at screening. Each subject received alternate therapy after a washout period (minimum two/maximum seven days). Subjects performed one morning treatment each day. Four subjects performed additional afternoon treatment. Treatments were given for 30 minutes with multiple frequencies and intensity settings (6 to 10) on each device.

Outcome parameters:

- Primary endpoint: during and one-hour post ACT
 - Mean wet sputum weight
- Secondary endpoint: HRCT scans before and after ACT
 - Visual quantification by Brody score
 - Functional Respiratory Imaging (FRI) [Figure 3]

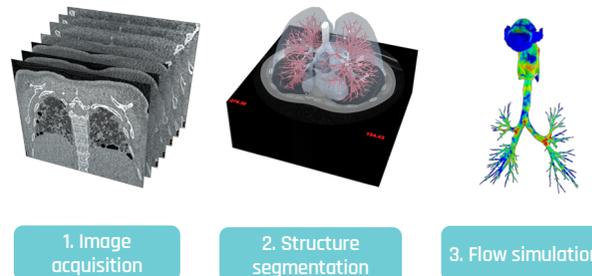


Figure 3: Functional Respiratory Imaging (FRI)

RESULTS AND DISCUSSION

Nine stable patients with CF were enrolled. One subject exited due to inability of completing study visits. Eight subjects completed the study.

Mean wet sputum weight was similar between mobile and standard device (6536_±8554 vs. 5801_±5824 mg, p=NS) [Figure 4].

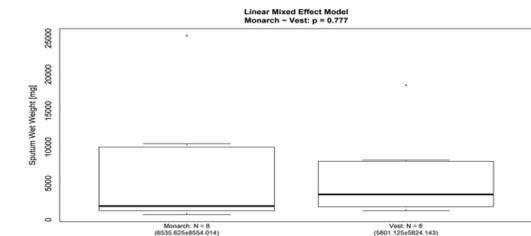


Figure 4.

Regarding **mode of action**, Brody scores showed statistically significant improvement after therapy with the mobile HFCWO device (57.71_±16.55 vs 55.2_±16.98, p=0.001). FRI showed statistically significant differences in airway geometry and patency for the mobile device after therapy (iRaw: 0.012_±0.013 vs 0.017_±0.013, p>0.05), suggesting mucus shifting [Figure 5].

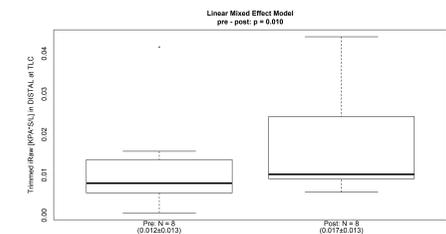


Figure 5.

CONCLUSION

- Sputum production of the mobile HFCWO is comparable to standard HFCWO
- Mobile HFCWO improves mucus transport in patient with CF according to interpretation of Brody scores and FRI

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References:

1. Ides K et al. Int J Chron Obstruct Pulmon Dis. 2012
2. De Backer et al. Radiology:257(3), 2010

