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Case Study:
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EVALUATION OF A MOBILE HFCWO DEVICE IN PATIENTS WITH CYSTIC FIBROSIS[1]

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INTRODUCTION

High-frequency chest wall oscillation (HFCWO) therapy for airway clearance is common in patients with cystic fibrosis (CF). A limitation is the requirement for AC power during therapy. A mobile HFCWO device that generates chest wall pressure and oscillating airflow comparable to standard HFCWO devices is now available. The goal of this study was to evaluate the effectiveness of this mobile HFCWO device (the Monarch® Airway Clearance System), compared to a standard HFCWO device (The Vest® Airway Clearance System).

METHODS

This was a randomized, open-label crossover study. Subjects received HFCWO with both devices. Inclusion criteria were age ≥ 15 years, stable CF medications (prior 4 weeks) and daily sputum production. Patients were randomized to the Monarch System or The Vest System on day 1. Each subject received alternate therapy after a washout period (2–7 days). Subjects performed 1 morning treatment each day. Four subjects performed an afternoon treatment, as well. Treatments were 30 minutes at multiple frequencies, with intensity settings of 6 to 10 on each device.

Subjects collected sputum during their 30-minute therapy and 1-hour post-therapy. Mean wet weight of sputum was compared. To further evaluate Monarch System therapy, CT scans were done before therapy and after sputum collection. Brody scores were performed on CT scans by a radiologist blinded to the study. Functional respiratory imaging (FRI)[2] was used to evaluate airway geometry using CT scans.

RESULTS

Eight ⑧ subjects completed the study. Mean wet sputum weight (Figure 1) was similar between the Monarch® System and The Vest® System therapy (6,536 ± 8,554 vs. 5,801 ± 5,824 mg, p=NS). Brody scores showed statistically significant improvement following therapy with the Monarch System. FRI results showed statistically significant differences in airway geometry and patency, pre-therapy vs. post-therapy with the Monarch System, suggesting mucus shifting. See Table 1 for Brody scores and FRI results.

CONCLUSIONS

The Monarch System was comparable to The Vest System for sputum production. Further evaluation of the Monarch System post-therapy found airway clearance improvement is shown by improved Brody scores and FRI results.

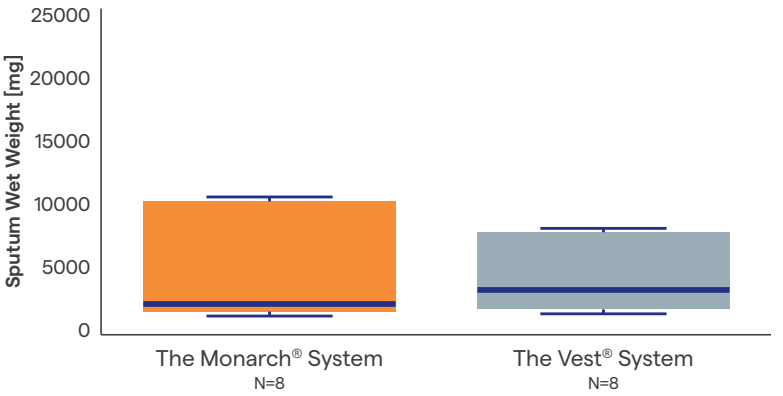

Figure 1. Comparison of Wet Sputum Weight, Monarch System vs. The Vest System (p=0.77)[1,3]

Parameter	Pre-Monarch System Therapy Measurements	Post-Monarch System Therapy Measurement	P-value
Brody Scores	57.71 ± 16.55	55.2 ± 16.98	p=0.001
FRI (iVaw)	49.442 ± 50.117	44.516 ± 49.637	p<0.001

Table 1. Brody Scores and FRI Measurements for the Monarch System

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References
[1] Leemans G, De Hondt A, Ides K, et al. Evaluation of a mobile HFCWO device in patients with cystic fibrosis. Pediatric Pulmonology. September 2018;53(S2):S1-S481.
[2] As described by: De Backer JW, Vos WG, Vinchurkar SC, et al. Validation of computational fluid dynamics in CT-based airway models with SPECT/CT. Radiology. December 2010;257⑧:854-62. doi: 10.1148/radiol.10100322.
[3] Analysis conducted using linear mixed effects model.