Physical therapy

Oscillating devices in cystic fibrosis

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Background

Intra or extra-thoracic oscillations are generated orally or externally to the chest wall by oscillating devices in order to create variable resistances within the airways, generating controlled oscillating positive pressure which mobilizes mucus in people with CF. There are a number of different methods used on their own or in combination with each other manual technique, breathing techniques and mechanical devices (Coppolo DP, 2021). The performance of these interventions may be unpleasant, uncomfortable, and time-consuming. Previously (Sisson JH et al, 2013) it has been suggested that Vest chest physiotherapy enhances airway clearance in CF stimulating clearance via increased Nitric Oxide metabolism analyzed by exhaled breath condensate (EBC).

Issues

1. To determine effectiveness of oscillating devices:

- to improve respiratory function;
- to improve mucus clearance;
- to improve other outcomes.

1. To determine acceptability of oscillatory devices compared to other techniques currently used for airway clearance.

What is known

Several clinical trials are available evaluating the efficacy of oscillating devices compared to different conventional airways therapies. 1 CDSR (Morrison L, 2017) identified 76 studies; 35 studies including 1138 participants met the inclusion criteria, although data were not published in sufficient detail in most of these studies to perform meta-analysis for difference in type of intervention and outcomes measured. Studies varied in duration from up to one week to one year; 20 of the studies were cross-over in design. Forced expiratory volume in one second was the most frequently measured outcome. Flutter, Acapella, Cornet, Quake, intrapulmonary percussive ventilation (IPV) are the most frequent oscillating devices orally generated while High Frequency Chest Wall Oscillation (HFCWO/VEST) generates an extra-thoracic oscillation. These devices were compared to other techniques currently used for airway clearance as PEP, breathing technique (AD, ACBT, conventional physiotherapy) and exercise. In particular, a multicenter Canadian randomized controlled study, included in the Cochrane review (McIlwaine MP, 2013), compared 51 patients with CF performing PEP with 56 patients performing HFCWO. There were significant differences between the two groups in the mean number of pulmonary exacerbations (1.14 for PEP vs 2.0 for HFCWO) and time to first pulmonary exacerbation (220 days for PEP vs 115 days for HFCWO, p=0.02). No significant difference in lung function, health-related quality of life scores or patient satisfaction scores were detected between the two groups. These results promote PEP and do not support the use of HFCWO as the primary form of airway clearance in patients with CF. Participant satisfaction was reported in 15 studies, but it was not specifically in favor of an oscillating device, as some participants preferred breathing techniques or techniques used prior to the study interventions. A randomized controlled study (Grosse-Onnebrink J, 2017) assessed Lung Clearance Index (LCI) as an outcome in 20 CF patients (7-34 years) hospitalized for infective pulmonary exacerbation. HFCWO improved (ie, decreased) the LCI by a median of 0.9 (range -0.45; 3.47; p=0.002); the LCI decreased in 15 of 20 intervention group patients. In five patients the decrease in LCI exceeded the CR (2.15), indicating a clinically relevant treatment effect; in five patients the LCI increased, but did not exceed the CR. The LCI did not change significantly in the control group patients. The effects of oscillating devices on the remaining secondary outcome measures such as exercise tolerance (as measured by recognized standard exercise tests-for example walk tests, step tests or cycle ergometry), quality of life indices, level of oxygen saturation in response to treatment, frequency of exacerbations, lung clearance index, did not provide any high level evidence.

1 CDSR (Wilson LM, 2018) included six Cochrane Reviews comparing an airway clearance technique, either as a single technique or as a combination of techniques, with no intervention, with coughing, or with another airway clearance technique The quality of the body of evidence comparing different airway clearance techniques on different outcomes was either low or very low. The Authors concluded that patients with CF should choose the airway clearance technique that best meets their needs, after considering comfort, convenience, flexibility, practicality, cost, or some other factor. More long?term, high?quality randomised controlled trials comparing airway clearance techniques among people with CF are needed.

1 CDSR (Morrison L, 2020), including 39 randomised controlled studies and controlled clinical studies, compared oscillating devices with any other form of physiotherapy in young (aged up to 16 years) and adult (16 years and above) CF patients with any degree of disease severity (total of 1114 participants). Interventions considered were: flutter; IPV; oscillating devices (OD). This systematic review showed that there was no clear evidence that oscillation was a more or less effective intervention overall than other forms of

physiotherapy; furthermore there was no evidence that one device is superior to another. The findings from one study showing an increase in frequency of exacerbations requiring antibiotics whilst using an oscillating device compared to positive expiratory pressure may have significant resource implications. More adequately?powered long?term randomised controlled trials are necessary and outcomes measured should include frequency of exacerbations, individual preference, adherence to therapy and general satisfaction with treatment. Increased adherence to therapy may then lead to improvements in other parameters, such as exercise tolerance and respiratory function.

One randomized, open-label, crossover pilot study (Leemans G, 2020) investigated the effectiveness of a mobile high-frequency chest wall oscillation (HFCWO) device for airway clearance. Wet weight of sputum collected during and after treatment was similar for mHFCWO and sHFCWO (6.53?±?8.55 vs 5.80?±?5.82; P?=?.777). The mHFCWO treatment led to a significant decrease in specific airway volume (9.55?±?9.96 vs 8.74?±?9.70?mL/L; P?<?.001), while increasing specific airway resistance (0.10?±?0.16 vs 0.16?±?0.23 KPA*S; P?<?.001). These changes were heterogeneously-distributed throughout the lung tissue and were greater in the distal areas, suggesting a shift of mucus. Changes were accompanied by an overall improvement in the Brody index (57.71?±?16.55 vs 55.20?±?16.98; P?=?.001). In conclusion, the newly developed mobile device provides airway clearance for CF patients comparable to a non-mobile sHFCWO device, yielding a change in airway geometry and patency by the shift of mucus from the more peripheral regions to the central airways.

One RCT (Trimble A, 2022) investigated the effect of three different physiotherapy methods to augment cough-clearance in addition to cough-clearance alone (high-frequency chest-wall oscillating vest, oscillatory positive expiratory pressure, and whole-body vibration) in 10 adults with CF. No differences were identified between any method of airway clearance, including cough clearance alone. Changes in certain small molecule concentrations in exhaled breath following airway clearance were identified. Due to the limitations of this study, the Authors do not believe the negative results suggest a change in clinical practice with regard to airway clearance. Findings pertaining to small molecules in exhaled breath may serve as future opportunities for study.

One retrospective case-control study at a single CF care center (Byrwa DJ, 2023) enrolling 50 CF patients (age < 18 years) evaluated lung function and measures of healthcare utilization in a case group (n=14), who used high-frequency chest wall oscillation or positive expiratory pressure devices at school, for at least 1 year after self-reported or an inadequate use at home identified by the physician. The study included a matched control group (n=36) composed of subjects with self-reported adequate use of ACT at home who were matched by age and gender. In the case group paired t-tests showed that after initiation of ACT at school, there were significant reductions in PEx requiring IV or PO abx (P = 0.010), total days of abx (P = 0.032), and visits to the CF care center (P = 0.037). There was no change in these outcomes in the matched control group. This is the first known study to highlight an initiative between a CF care center and schools which utilized airway clearance devices at school to ensure pediatric CF patients completed ACT. Through increased adherence, this relationship was associated with improved health outcomes. Use of alternative strategies may help patients with CF sustain adequate airway clearance.

A lot of trials have been performed or underway.

- One trial (NCT02750722) has been completed in 2017 in adult patients with CF in order to compare 30 minutes of moderately intense cycling exercise in 4-min intervals at 75% of their maximal heart rate and interspersed with 2-min resting periods during which 6-8 breathing maneuvers incorporating Flutter® breathing maneuvers with a single bout of moderately intense cycling exercise alone on sputum viscoelasticity and the diffusion capacity of the lungs;
- one trial (NCT02277626) has been completed in 2015 in order to compare the efficacy, as assessed primarily by sputum weight, of these two different devices (the Electroflo 500 and VEST therapy) on airway clearance (AC) in CF patients with mild to moderate lung disease, who have stable lung health and perform AC at home as part of their routine therapeutic regimen;
- one randomized parallel open label study (NCT01057524) has been completed in 2016 with the aim to evaluate whether the addition of high frequency chest wall oscillation to twice daily supervised physiotherapy is as effective as the addition of self treatment in facilitating recovery from an acute infective pulmonary exacerbation, as measured by improvement in lung function (FEV1);
- in two randomized trials (Wheatley CM, 2018) 10 and 11 mild to moderate CF patients were recruited for study I and II, respectively to evaluate the influence of the Vibralung Acoustical Percussor on pulmonary function and sputum expectoration in individuals with CF. These studies concluded that Vibralung was well tolerated and caused no detrimental changes in pulmonary function metrics. The Vibralung appears to be a safe ACT in individuals with CF;
- a Belgian randomised controlled single-blind cross-over trial (ISRCTN75391385) has been completed in 2014 in order to evaluate the effect of intrapulmonary percussive ventilation on Pseudomonas aeruginosa biofilm formation and virulence in patients with CF over 6 years of age. For each study participant, three different physiotherapy regimens have been tested during three different hospitalisation periods: autogenous drainage, IPV low frequency (200 bpm) and IPV high frequency (400 bpm). Results have not been published;
- one randomized, crossover trial (NCT01753869) has been terminated in 2012 in patients with CF 18 years and older to compare the effect of ACTs using Acapella after hypertonic saline solution 7% (HTS) inhalation with ACTs during HTS inhalation in adult CF patients during day 10-14 of a hospital admission for treatment of a pulmonary exacerbation. The primary objective was to compare the change in lung clearance index at 90 minutes post treatment with ACTs after HTS inhalation with ACTs during HTS inhalation. Results have not been published;

  A 1-month duration Irish study including 31 participants has been recently performed (O'Sullivan KJ et al, 2021) in order to evaluate whether a daily disposable Oscillating positive xpiratory pressure (OPEP) device (the UL-OPEP) can mitigate the risk of contamination and eliminate the burdensome need for cleaning devices. Assessment of lung function pre- and post-intervention by spirometry, as well as Lung Clearance Index and quality of life assessed using the Cystic Fibrosis Questionnaire showed that disposable OPEP device maintained patients' lung function during short term use (? 1 month) while reducing the risk of airway contamination associated with ineffective cleaning.

Unresolved questions

Oscillatory devices are a recognized efficient airway clearance therapy, but they are not superior to any other technique nor one device is superior to another. Studies on this topic are generally poorly designed based on the small sample sizes, insensitive outcome measures, different duration of intervention and the large heterogeneity of treatments before enrollment and during the studies, making impossible to pool results from different studies. In addition there may also be a requirement to consider the cost implication of devices over other forms of equally advantageous airway clearance techniques. Future research including longer parallel studies with control groups would add information with regard to treatment efficacy and safety of oscillating devices alone or in combination with other therapies.

As there is no appreciable difference between the devices and therapies used in airway clearance the health care program should be defined considering a cost-benefit analysis for each individual patient. Patient preference and acknowledgement are also important, as well as the impact of the device on the individuals at particular stages of their disease. This would enable the appropriate selection and inclusion of airway clearance techniques or devices into the management of the individual, also taking into consideration the potential effect of highly effective modulator therapies with ETI treatment on ACTs use and the need of nebulised treatments (Almuhlem M et al, 2022) in the future.

Keywords

Airway clearance technique; Chest physiotherapy - Devices; Oscillating devices;