The Value of Conducting Laboratory Investigations on Airway Clearance Devices

The mucociliary escalator and cough reflex maintain optimal function of the respiratory system by facilitating secretion clearance and preventing airways obstruction. However, many factors, including the aging process, tobacco use, and environmental exposures, interfere with secretion clearance by reducing the efficacy of ciliary structure and function.[1] Disease processes may also adversely impact the body's natural ability to remove airway secretions. Progressive neurodegenerative conditions inhibit the normal cough reflex. Chronic obstructive pulmonary disorders such as cystic fibrosis and bronchiectasis alter the production and composition of mucus, and mucociliary clearance disorders, such as primary ciliary dyskinesia, reduce the efficacy of ciliary structure and function. Airway obstruction and structural damage to the airways and lung parenchyma result from recurring infection, inflammatory changes, and secretion retention.

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Technological and clinical advances offer practitioners a variety of commercially available devices to aid in the mobilization and expectoration of airway secretions. As respiratory therapists we may be called upon to select and incorporate a particular airway clearance therapy into a treatment plan for a patient or particular cohort of patients with a specific disease process. The scientific literature offers a plethora of information with regard to the therapeutic effectiveness of various airway clearance techniques and devices available for secretion removal. However, systematic reviews of airway clearance research suggest that a number of methodological limitations exist. Small sample sizes, lack of reproducibility, sparse use of sham therapy, and reports limited to short-term outcomes with respect to a single treatment session contribute to the lack of evidence to support the use of a particular device or breathing technique.[2,3]

In practice, clinicians must have integral knowledge of airway clearance techniques, the patient's cognitive ability and disease process, as well as therapeutic goals, in order to devise an effective plan of care. The appropriateness of a particular airway clearance device may be difficult to ascertain. Manufacturer's instructions for use may be vague and often lack the specifications clinicians need to understand the effects of the device.

The Flutter VRP1 (Varioraw, Aubonne, Switzerland) is an example of an oscillatory positive expiratory pressure (OPEP) device evaluated clinically and found to assist in secretion clearance. When compared to conventional forms of airway clearance, such as autogenic drainage, active cycle of breathing, or chest physiotherapy, the Flutter was found to have similar effects on oxygen saturation, pulmonary function, arterial blood gas values, symptoms scores, and hospital duration of stay.[4-6] The Flutter is pipe-like in appearance and has a perforated cap that contains an inner cone and a steel ball. As exhaled gas passes through the device, the steel ball vibrates vertically within its casing, causing airflow vibrations or oscillations. The angle at which the device is held affects the amount of force needed to cause the steel ball to vibrate, which in turn affects the expiratory flow and controls the frequency and amplitude of the oscillations and positive expiratory pressure (PEP).[7]

Since patients with airway clearance abnormalities have varying degrees of flow limitation, clinicians interested in using this device should know how the device will perform across the spectrum of flow ranges (normal expiratory flow to severe obstruction). When initiating therapy, it would be valuable to know the effect expiratory flow rate and the angle at which the device is held have on mean PEP, pressure amplitude, and oscillatory frequency. This information may also be useful in recommending changes in the device incline as the patient's flow limitations change during the course of treatment, so that an amplitude and PEP required for therapeutic effectiveness are produced. This can be best illustrated with cystic fibrosis patients treated for an exacerbation. It is not uncommon for a patient to have lower forced expiratory volume in the first second at the initiation of treatment and an improvement during the course or near the end of the treatment regimen. Although useful, it is uncommon to find such detailed information regarding the physical principles of operation in the manufacturer's marketing or user literature.

Perhaps the most valuable information clinicians can rely on is from bench or laboratory experiments that investigate the performance characteristics of airway clearance devices. These studies are of value because the information provided assists clinicians to better understand how the device will perform as expiratory flow produced by the patient and resistance to flow provided by the device vary, without investing the financial and human resources needed to conduct a formal device evaluation.

To properly evaluate OPEP devices, sensitive flow and pressure transducers, as well as specialized data-acquisition equipment are required. In the evaluation of devices that produce high-frequency airflow oscillations, the data-acquisition system must have a frequency response and data-sampling rate high enough to faithfully record the signal. A rule of thumb is provided by the Nyquist theorem, which states that the sampling rate should be at least 2 times the highest frequency of the measured signal from the device being tested.[8]

Since the Flutter has an oscillatory frequency in the range of 8–26 Hz,[9] sampling at a rate of at least 52 Hz is needed. It is not uncommon for laboratory investigations of the performance characteristics of OPEP devices to exceed the minimum sampling recommendations in order to accurately capture these high-frequency signals. Published laboratory work on performance characteristics of OPEP devices, for example, have far exceeded the minimum requirements and used data-acquisition equipment with a sampling rate of 200 Hz.[10]

In this issue of the Journal, researchers from Brazil recognized the shortcoming of the manufacturer's instructions for use, in addition to the value of analyzing performance characteristics of an oscillatory PEP device, the Flutter VRP1.[11] Flow ranges of 0.2–2.0 L/s were tested, in 0.2 L/s increments, to represent the spectrum of expiratory flow rate limitations (severe to not severe) patients exhibit clinically. Continuous lower flow rate range was used in this particular study to coincide with how patients are instructed to use the device in the clinical setting.

The technique is twofold. The first step is designed to loosen secretions from the bronchial walls and facilitate cephalad mobilization. Specifically, patients are instructed to take a slightly larger than normal tidal volume breath, but not to completely fill the lungs. During exhalation the patients are to maintain a steady exhalation for at least 4 seconds without exhaling to functional residual capacity. Normal passive exhalation would result in an exponential decay flow waveform rather than a constant flow throughout the expiratory maneuver. Typically, patients are asked to perform this maneuver for 5 to 10 breaths before progressing to the second step, which assists with expectoration. During this portion of the therapy the patient performs a forced exhalation of a larger than tidal volume breath through the device. Only 1–2 breaths are performed during this portion of the therapy. It is this portion of the therapy that generates the short bursts of high flows.

The results of this study coincide with similar laboratory investigations that suggest that mucus clearance is enhanced by short bursts of expiratory flow caused by the OPEP device, which result in high-flow spikes in the airways, which mobilize or drag secretions cephalad.[10] The authors provide useful summary charts that detail the relationship between the Flutter's output (mean pressure, resistance, oscillatory frequency, and oscillatory flow amplitude) as functions of expiratory flow. While the sampling rate of the author's data acquisition system was adequate (100 Hz), the frequency responses of the pressure and flow sensors were not documented.

These data give practitioners a reference to set the inclination, based on the patient's expiratory flow characteristics, to obtain what the authors describe as "most favorable" results or the inclination that would produce airflow oscillations that would theoretically optimize mucus mobilization. The authors did note a difference in the oscillation frequency at different flow rates and inclinations; however, they comment on the stability of the pressure waveforms under these varying conditions.

It would be interesting to note if variations in amplitude, and at the extremes of the flow ranges tested, and different inclinations, were comparable to the results of previously published works. Volsko et al[10] reported that although the Flutter produced high-frequency oscillations in the range of 20–30 Hz at the extremes of the flow rates tested (5 L/min and 30 L/min), the amplitude of the waveform varied greatly (ie, 10–100 mm Hg on a flow of 30 L/min). This would theoretically compromise the OPEP device's ability to consistently generate the short bursts of flow required to enhance secretion transport.

This paper by Alves[11] helps to increase a respiratory therapist's knowledge of the operation and application of this OPEP device for patients with varying degrees of expiratory flow impairments. Alves and colleagues offer

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The author reports no conflicts of interest related to the content of this editorial.

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encouragement for further evaluation of OPEP devices and the application to clinical practice.

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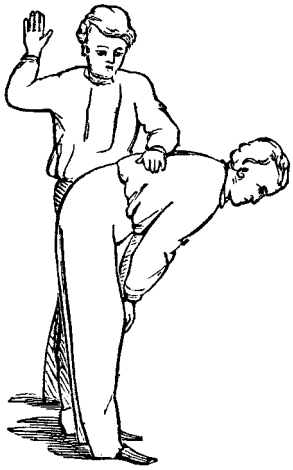

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