



Clinicians and Patients Prefer vPEP[®] vs. Other Handheld Oscillatory Positive Expiratory Pressure (OPEP) Devices

Michael Pedro, MD, Medical Director and Vice President, Vyaire Medical

Company Statement:

This white paper is shared with our healthcare colleagues to increase knowledge about oscillatory positive expiratory pressure (OPEP) devices and their use in clinical practice. This paper reflects the results of survey of 24 healthcare professionals and patients who OPEP devices. Vyaire Medical is not seeking to promote, endorse or advise the use of its products for patients in need of ventilation assistance. The use of OPEP devices must first be reviewed and evaluated by each facility's medical and administrative staff before implementation.

Introduction:

Oscillatory positive expiratory pressure (OPEP) devices help clear excess secretions from the lung and reduce gas trapping to promote ventilation. OPEP devices combine high frequency oscillations with PEP when the patient exhales through the device. The positive pressure enables airflow behind secretions and the oscillations result in vibrations that can displace and decrease the viscosity of bronchial secretions and thus allow them to be cleared from the lungs. OPEP devices are used for patients with a variety of conditions, including chronic obstructive pulmonary disease (COPD), atelectasis, pulmonary emphysema, chronic bronchitis, bronchiectasis, cystic fibrosis, and asthma.

The Role of Mucus

Mucus in the lungs helps keep the airways moist and functioning, aiding in the humidification of inspired air. Healthy lungs produce about two liters of mucus daily from glands within the epithelial lining of the interior airway surface and the connective tissue beneath this epithelium.¹

In addition to water and the glycoprotein mucin, mucus contains electrolytes, lipids, proteins from plasma and cellular debris.^{2,3} These components

give mucus a sticky quality, which aids its ability to trap dust and pathogens.

Within the lungs, the mucociliary system of the trachea and bronchi move mucus upwards for swallowing. At the lung bronchi, fewer cilia are present and mucus is less viscous.¹

Illness or damage to the respiratory system disrupts the mucociliary system and can inhibit breathing.⁴ For example, patients with pneumonia, productive chronic obstructive pulmonary disease (COPD), cystic fibrosis (CF),

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pulmonary emphysema, chronic bronchitis, bronchiectasis, or asthma secrete too much and thicker mucus while also experiencing reduced mucociliary transport.⁵

Coughing associated with these illnesses can help expel the mucus secretions as sputum. Cephalad airflow bias, the airway narrowing during exhalation that speeds air and increases shearing forces, also helps move mucus.

However, if their mucus production overwhelms the normal clearance mechanisms and mucus plugs can develop, the health consequences may include ventilation-perfusion mismatch, atelectasis and reduced gas exchange.⁶

OPEP Therapy

Chest physiotherapy helps remove excess lung secretions and “break the cycle of obstruction, infection, inflammation, and damage to pulmonary tissue”⁴ associated with respiratory disease. For respiratory patients who need more assistance to clear mucus from the lungs and produce sputum, an oscillating positive expiratory pressure (OPEP) device is recommended. These devices also reduce gas trapping to promote a patient’s ventilation.

As the name implies, OPEP devices combine high-frequency oscillations with PEP as the patient exhales through the device’s threshold resistor. The oscillations cause vibrations that displace bronchial secretions and decrease their viscosity, enabling their clearance from the lungs. The PEP enables airflow behind secretions to move them away from the airway walls while forcing the walls to remain open.

A clinical concern during the use of OPEP is inspiratory flow bias, indicating the airflow during inhalation is too high and could push secretions further down the airway.⁷ This bias can occur when a patient takes a fast, deep breath in and exhales slowly. To counter this, patients are counseled to take long, slow inhalation and exhale with more force than their usual breathing.⁷ However, a closed, vs. open OPEP device design can aid in slowing inhalation. A closed device incorporates a one-way valve to slow inhalation via slight resistance, which helps

maintain an open and unobstructed airway during inhalation. Open OPEP devices lack this valve.

vPEP by D.R. Burton

The vPEP[®] by D.R. Burton (Vyaire Medical, Mettawa, IL) is a compact, hand-held closed OPEP device that is intuitive, ergonomic and easy to clean and able to transition from hospital to home. A vPEP[™] HC device also is available for home settings. Both designs feature a patented flapper design and offer adjustable resistance.

Previous studies demonstrated the superior clinical performance of the vPEP compared to other OPEP devices, as measured by multiple metrics including oscillation amplitude and expiratory flow bias, as demonstrated with flow-volume loops across different resistances and tidal volumes.^{8,9}

Of note, the vPEP flow amplitude successfully loosened secretions and decreased mucus viscosity. Once loosened, the vPEP expiratory pressure and higher expiratory flow bias, compared to two challenge devices, mobilized secretions for more effective expelling from the lung.

The vPEP device’s higher mean expiratory pressure offered the added benefit of potential improvement in collateral ventilation and efficacy.

With these documented vPEP clinical advantages, we surveyed clinicians and users of the vPEP to learn about their experiences and opinions of the vPEP device relative to other OPEP devices. This paper presents the results of this survey.

Survey Design

We fielded an eight-question, multiple-choice survey from July 1 to August 18, 2020, to learn clinicians’ and patients’ opinions about the vPEP device compared to other OPEP devices (Appendix).

We conducted the online survey using SurveyMonkey Inc., via distribution of the link via email to vPEP customers in the United States. All of the contacted individuals previously had switched to using the vPEP device from another OPEP device.

Of the 26 respondents opening the SurveyMonkey link, 92 percent (24) completed the survey. Two participants skipped one question, while another participant skipped four questions. Data from these incomplete surveys were included in the analyses.

Five of the eight questions asked respondents to answer their level of agreement with a statement using a five-level Likert scale: *strongly disagree*, *disagree*, *neutral*, *agree*, and *strongly agree*. The other three questions offered a choice of descriptive answers.

The first four questions asked clinicians about their experience with and opinion of the vPEP, while the second four questions captured that of patients.

We visualized the distribution of responses to these questions using diverging stacked bar plots. We then compared the proportion of patients with a *neutral* or *agree* responses to the proportion of *disagree* answers using the one-sample z-test for proportions.

As an additional analysis, we applied a linear scale from -2 (*strongly disagree*) to 2 (*strongly agree*), calculated the mean response and performed one-sample t-tests to compare the mean response to neutral (i.e., score = 0).

Results

Nearly all clinicians (22/24, 92%) preferred to use the vPEP device compared to other OPEP devices ($p < 0.0001$), as measured by their responses to the first question.

Responses to the second question, which explored the primary reason why the clinician switched to vPEP from a previous OPEP device, revealed that they nearly split between the vPEP's clinical advantages (8/24, 33%) and the relatively lower price of the device (11/24, 46%). When offered an open response as part of the second question, respondents' cited examples of clinical advantages included expiratory flow bias, oscillation flow amplitude, and oscillation frequency.

Most clinicians indicated that they were neutral, agreed, or strongly agreed that the vPEP cleared more secretions than other OPEP devices (21/23, 91%, $p < 0.0001$), as asked in question three. Assigning a linear scale to these responses from -2 (Strongly Disagree) to 2 (Strong Agree), the clinicians' average rating was positive (0.6, $p = 0.16$).

In answers to question four, the clinicians noted that the vPEP device was effective for a range of patients. Specifically, half reported the device had the best results among patients with COPD (11/22, 50%), while 10 out of 22 (45%) reported best results with post-operative and atelectasis patients. One clinician noted successful results with a patient who has CF.

Patients agreed with clinicians that the vPEP, vs. other OPEP devices, cleared more secretions (mean = 1.6, $p = 0.014$), with only two patients (9%) disagreeing. Patients also reported the vPEP was more comfortable (mean = 1.8, $p = 0.012$), easier to use (mean = 2.6, $p = 0.0002$), and improved their quality of life (mean = 1.4, $p = 0.016$).

Figure 1 visualizes the results of the five questions asked on a Likert scale.

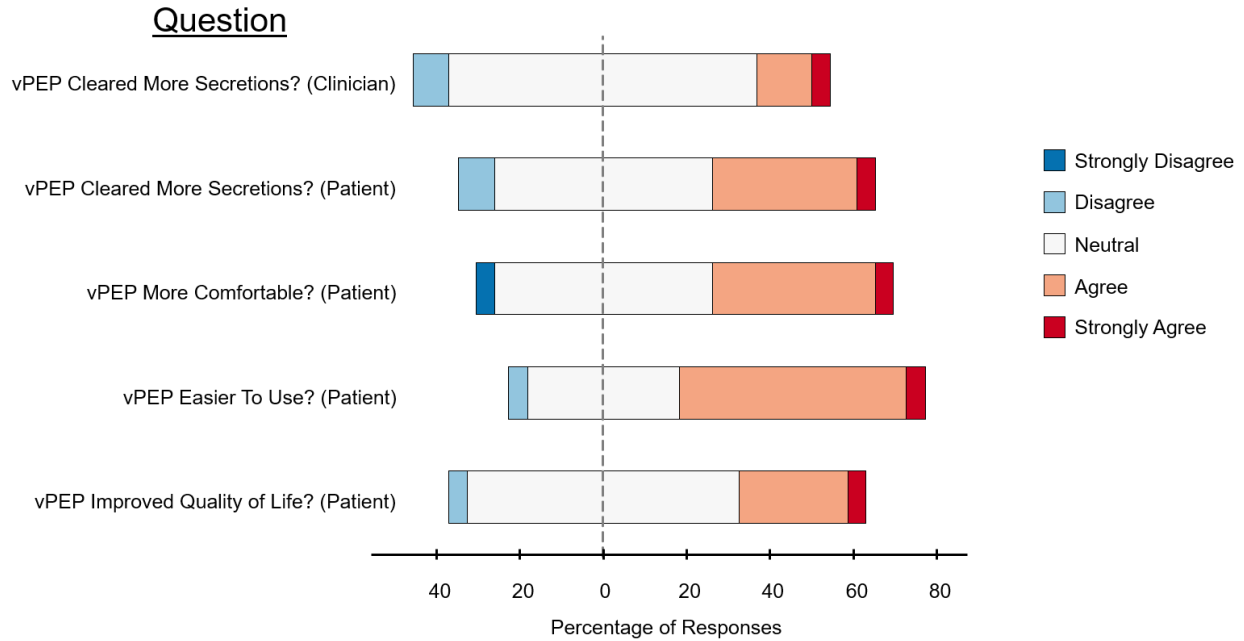


Figure 1. Distribution of vPEP Survey Responses.

The stacked bar graphs visualize the Likert scale responses from Strongly Disagree (darker blue) to Strongly Agree (dark red). The width of bar segments is proportional to the percentage of respondents providing that answer. The bars representing the neutral responses (white) are centered on the y-axis. Note that all five stacked bars are biased to the right because more respondents agreed than disagreed with the questions.

Discussion

This survey conducted on a small number of clinicians and vPEP users shows a strong preference for the vPEP based on clinical experience and patient outcomes compared to other OPEP devices.

Nearly all clinicians and patients agreed that the vPEP performed the same or better at clearing secretions. Notably, users also reported the vPEP was more comfortable, easier to use, and improved their quality of life.

All surveys have certain limitations associated with them. Particularly, respondents may not feel

comfortable answering honestly or giving answers that unfavorably present themselves. Further, the survey respondents total did not reach the set goal of 35 responses, yielding a small sample size. However, many of the comparisons still reached statistical significance.

The results of this survey supplement previous studies demonstrating the superior clinical performance of the vPEP.^{7,9} The survey’s capturing of evidence from real-world experience may benefit the improvement of respiratory patient care in hospitals and other clinical settings.

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Appendix

vPEP Survey

Clinician Satisfaction

1. I prefer to use vPEP vs other OPEP devices for my patients
 - a. Yes
 - b. No

2. The reason I switched my OPEP device to vPEP was because of:
 - a. vPEP's clinical advantages (i.e. greatest expiratory flow bias, oscillation flow amplitude and oscillation frequency)
 - b. Price
 - c. The transparent device made it easy to identify when it needs to be cleaned
 - d. I wasn't happy with the clinical results from my previous OPEP device
 - e. I haven't noticed significantly better results with vPEP
 - f. Other (specify below)
 - i. _____

3. I noticed vPEP cleared significantly more secretions compared to other OPEP devices.
 - a. Strongly Disagree Disagree Neutral Agree Strongly Agree

4. A specific subset of my patients that I have noticed the best results from vPEP in is:
 - a. COPD
 - b. Cystic Fibrosis
 - c. Post-operative
 - d. Atelectasis
 - e. Other (specify below)
 - i. _____

Patient Satisfaction

5. I felt vPEP was more effective at clearing secretions compared to other OPEP devices
 - a. Strongly Disagree Disagree Neutral Agree Strongly Agree

6. vPEP was more comfortable to compared to other OPEP devices.
 - a. Strongly Disagree Disagree Neutral Agree Strongly Agree

7. I felt that vPEP was easier to use compare to other OPEP devices.
 - a. Strongly Disagree Disagree Neutral Agree Strongly Agree

8. I feel that vPEP improves my quality of life.
 - a. Strongly Disagree Disagree Neutral Agree Strongly Agree