No-Leak Speaking Valves and Respiratory Muscle Training: A Perfect Pairing for Early Intervention in the ICU

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Introduction

Research supports the use of respiratory muscle training (RMT) to improve ventilator weaning outcomes, swallow safety, and cough strength (Pitts et al., 2009; Elkins & Dentice, 2015). The use of a no-leak speaking valve, such as the Passy Muir® Valve (PMV®), allows patients with tracheostomies, even those who are ventilator-dependent, to participate in expiratory muscle training (EMT).

Failure to wean from mechanical ventilation is experienced in approximately 10-15% of patients who are mechanically ventilated and has been determined to worsen clinical outcomes (Martin et al., 2011). Critical illness myopathy, including weakness and deconditioning of respiratory muscles, is a common sequela of prolonged mechanical ventilation and may be a factor in failure to wean from mechanical ventilation (Puthucheary et al., 2013; Goligher et al., 2016). Of patients who require mechanical ventilation for more than 48 hours, an average of 9.6% require tracheostomy (Abril et al., 2021). On average, this means that more than 84,000 tracheostomies are performed in the United States each year (Abril et al., 2021). With the COVID-19 pandemic, there was a global surge in critically ill patients with significant respiratory deficits who required mechanical ventilation, and a large portion of those patients receiving tracheostomies (McGrath et al., 2020). Early tracheostomy in critically ill ICU patients has shown to reduce need for sedation (McCredie et al., 2016; Mallick & Bodenham, 2010), allowing patients to participate in early rehabilitation intervention in the ICU, which has shown to significantly improve outcomes (Tipping et al., 2016). Various interventions exist for patients to actively participate in to assist with weaning from the ventilator; however, respiratory muscle training may prove to be another area of early rehabilitation intervention that improves patient outcomes (Bissett et al., 2020).

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A ventilator dependent patient practices EMT with a threshold device and the PMV®007 in place.

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Benefits of Early Intervention

The benefits of the Passy Muir® Tracheostomy & Ventilator Swallowing and Speaking Valve (PMV) for patients with tracheostomies have been extensively researched, including the effects on improving upper airflow, improving swallow function, reducing aspiration, and improving secretion management (Elpern et al., 2000; Davis & Stanton, 2004; O'Connor et al., 2018). Another benefit of the use of the PMV is improved lung recruitment and faster weaning, as investigated with patients on mechanical ventilation (Sutt et al., 2016). Introduction of EMT to patients who are ventilator-dependent with tracheostomies is best approached with the use of the no-leak speaking Valve. Both EMT and PMV are complementary in targeting deficits seen in critically ill patients, such as dysphagia, reduced cough effectiveness, and poor airway clearance. Since the PMV closes the system, allowing the patient to exhale through the upper airway, use of the PMV for patients with tracheostomies during RMT is necessary to allow good upper airflow. The combination of EMT and PMV may be beneficial for improving the deficit areas often seen in the critically ill, as well as assisting with weaning from mechanical ventilation and the tracheostomy.

With increasing evidence that early intervention strategies, such as early mobilization, in intensive care are beneficial (Hodgson et al., 2018), the implementation of RMT programs in the population of patients who are on mechanical ventilation with tracheostomy is gaining popularity. Not surprisingly, research shows respiratory muscle weakness is much more prevalent than limb muscle weakness in patients in the ICU setting (Dres et al., 2017). RMT allows for a targeted approach that is low-cost and relatively low-risk to increase respiratory muscle strength, which in turn could aid in ventilator weaning (Tonella et al., 2017; Elkins & Dentice, 2015); improve swallow function (Pitts et al., 2009); and improve cough strength (Pitts et al., 2009) – leading to improved secretion management.

Respiratory Muscle Training with Mechanical Ventilation

RMT includes both inspiratory muscle training (IMT) and expiratory muscle training (EMT). IMT targets the muscles of inspiration, including the diaphragm and external intercostals, while EMT targets the muscles of expiration, including the abdominal muscles and internal intercostals (Sapienza & Troche, 2012). Several studies have demonstrated improvements in ventilator weaning rates with IMT (Martin et al., 2011; Tonella et al., 2017; Cader et al., 2010). Research demonstrates that EMT improves expiratory muscle strength, swallow function, voluntary cough, and reflexive cough strength across multiple patient populations (Pitts et al., 2009; Park et al., 2016). Although clinical studies specific to the use of EMT in patients with tracheostomy and mechanical ventilation are limited, if one also considers that using a PMV closes the system and restores more normal physiology, then applying current research of other patient populations supports EMT as a viable therapy approach in the patient population with tracheostomy and mechanical ventilation.

IMT, EMT, or a combination of both may be indicated when creating a therapy plan; this will vary by individual patients and goals of therapy. Introducing EMT may be considered once a patient is able to tolerate the PMV, even while still on ventilatory support. Since EMT is most effective when patients exhale from the mouth and nose, having a closed system is most beneficial. Because the PMV is a no-leak Valve, when it is in place, patients breathe out of their mouth and nose and may use EMT devices.

One special consideration is that using an EMT device is considered an aerosol generating task and training includes repetitions of forceful exhalations. In today's COVID-19 environment, aerosol generating procedures are of increased concern. For this reason, EMT may be approached with a disposable anti-bacterial filter that is placed directly on most devices to limit the spread of airborne pathogens. On the other hand, IMT may be performed using a pressure threshold device connected directly to the tracheostomy. However, for IMT with a patient on mechanical ventilation, the patient is briefly taken off ventilator support to perform the IMT exercises (Bissett et al., 2018). For this reason, IMT training with patients who are ventilator dependent must be conducted in conjunction with a trained respiratory therapist (RT).

If the patient is on ventilatory support, a respiratory therapist works with the speech-language pathologist (SLP) for in-line PMV placement. The RT is responsible for ventilator adjustments during the use of an in-line PMV. Once the PMV is in place, air flow is redirected through the upper airway and EMT therapy initiated.

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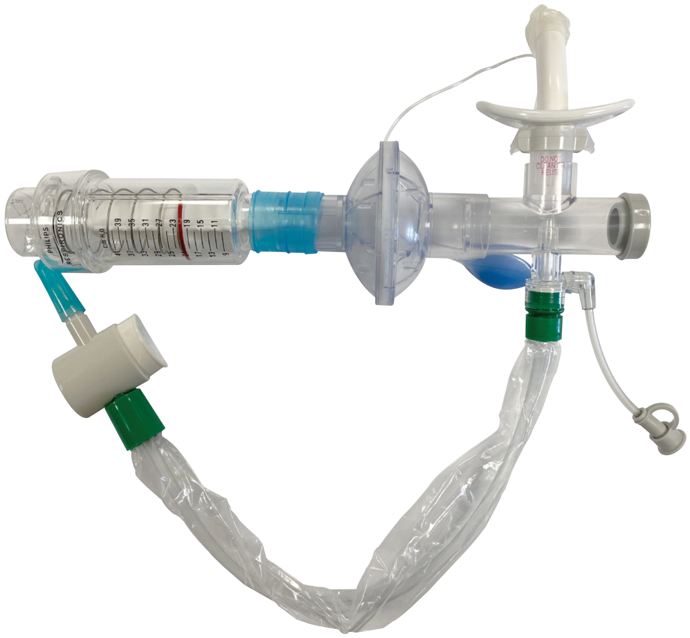

Setup for IMT and EMT with pressure threshold devices and bacterial filters.

RMT Treatment Considerations

When working with this patient population, it is important to note that many patients will require very low resistance, frequent rest periods, and a limited number of repetitions. Target resistance may be established using a manometer to measure maximum expiratory pressure (MEP) and maximum inspiratory pressure (MIP) (Evans & Whitelaw, 2009). Training will often begin at 50%-75% of a patient's MIP or MEP, and devices can be adjusted weekly based on patient progress. Another useful tool is a peak cough flow meter which can help establish a baseline and document changes in cough strength. Therapists should constantly be monitoring vital signs and paying close attention to changes in SPO_2 (oxygen saturations) levels, HR (heart rate) and RR (respiratory rate). Some considerations for using either inspiratory or expiratory muscle training are presented in Table 1.

RMT Device Considerations

There are several devices that may be considered for RMT, choosing the type of the device will depend on intended goals (see Table 2). Devices that are often used include incentive spirometers, resistive training devices, and pressure threshold devices. An incentive spirometer is often utilized by a patient post-surgery to maintain an open airway and improve lung volumes. Incentive spirometers are affected by airflow and have been found to have insufficient training resistance for RMT (Larson et al., 1988). A resistive training device is adjusted by changing the size of the inner diameter, requiring increased respiratory muscle force to pass air as the diameter decreases. These devices also may be affected by the airflow rate of the user. For example, if the patient were to breathe slowly enough, the load would not be as significant (Sapienza & Troche, 2012).

Pressure threshold devices have a pressure relief valve which creates an isometric load on the muscles being targeted. These devices are calibrated and not susceptible to changes in the users' airflow rate, allowing for a specific and reproducible load during training (Sapienza & Troche, 2012). This type of training adheres to the principles of neuroplasticity (Kleim & Jones, 2008), which include repetition, intensity, overload, and specificity; this adherence further supports its effectiveness as a tool in rehabilitation. The pressure load can be accurately measured and increased to target specific muscle groups, including the diaphragm, internal and external intercostals, and the submental muscle group, all essential to the functions of cough and swallow. Although RMT devices are respiratory trainers, evidence from research demonstrates that the benefits of strength-training these muscles transfers to the functions of cough and swallow (Pitts et al., 2009).

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Table 1

Inspiratory Muscle Training (IMT)	Expiratory Muscle Training (EMT)
• Abductor Vocal Fold Paralysis[1] • Ventilator weaning (Paresis/Paralysis of Diaphragm)[2]	• Dysphagia[3] • Cough (airway clearance, airway protection)[4] • Voice/Breath Support for Speech[5]

[1] Baker et al. (2003) [2] Vorona et al. (2018) [3] Tawara et al. (2018) [4] Pitts et al. (2008) [5] Darling-White & Huber (2017)

Table 2

Device Name	Device Features	Ranges	IMT/EMT
The Breather	Resistive Trainer	- 52 cmH_2O to 30 cmH_2O	IMT/EMT
EMST75 Lite	Pressure Threshold	0 cmH_2O to 75 cmH_2O	EMT
EMST150	Pressure Threshold	30 cmH_2O to 150 cmH_2O	EMT
Respironics Threshold PEP	Pressure Threshold	0 cmH_2O to 20 cmH_2O	EMT
Respironics Threshold IMT	Pressure Threshold	9 cmH_2O to 41 cmH_2O	EMT

IMT = Inspiratory Muscle Training EMT = Expiratory Muscle Training

RMT may not be appropriate for everyone, establishing inclusion and exclusion criteria for patients in specific facilities is important. Discussing treatment with your medical team and consulting the MD for clearance when working with this population is recommended. Contraindications to RMT include pregnancy, ruptured eardrum, abdominal hernia, or recent abdominal surgery. Other considerations that would warrant clearance from a physician include severe reflux, uncontrolled hypertension, and severe asthma (www.emst150.com). When considering candidates for an RMT protocol, clinicians consider the amount of pressure daily tasks require. For example, speech production requires 5-10 cm H_2O, cough requires 100-200 cm H_2O, and having a bowel movement requires 200-300 cm H_2O (Sapienza, 2021). If a patient is not able to produce pressure within those ranges, then RMT may be an intervention to consider.

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Considerations for Patients with Tracheostomy

Because many of these patients are medically complex, a multidisciplinary approach is particularly beneficial when implementing a RMT program in the population of patients who have a tracheostomy or mechanical ventilation. Development of a protocol for RMT in this population will require direct collaboration with respiratory therapy and will often require physician clearance, prior to initiating therapy. Education and training should be provided across disciplines, including respiratory therapy, speech-language pathology, physical therapy, occupational therapy, physicians, and nursing. In addition, involving multiple disciplines may improve compliance and adherence to the program. Many of the goals targeted with this training are shared across disciplines. For example, a general goal for a patient using EMT may be to improve cough strength, which may be a goal for PT, SLP, and RT. Finally, another notable, albeit more anecdotal, benefit of implementing an RMT program in the population of patients who have tracheostomies is a noticeable increase in patient motivation. RMT allows the patient to take an active role in the weaning process. Traditionally, weaning from the tracheostomy or mechanical ventilation is mostly approached with a trial-and-error mentality. New ventilator and oxygen settings will be attempted. If a patient is not able to tolerate the change, they are returned to their previous settings. This process may often be frustrating for patients, especially for those patients who require long-term ventilator use, as they seemingly have a passive role in the process. RMT allows patients the opportunity to engage in the process and have an active role. In addition, because RMT devices can be used for years with proper cleaning, patients are provided with a tool that continues to be beneficial throughout their continuum of care.

Conclusion

There is a constellation of deficits, including weakness and atrophy of the respiratory muscles, that can arise from prolonged ventilator use in patients who are critically ill, many of whom will eventually require a tracheostomy. Weaning patients from the ventilator is an important step in their recovery from critical illness; however, across the continuum, this process can often be frustrating for patients. Patients do not often have opportunities to assist or control the process of weaning from the ventilator, and this may be an approach that allows patients to participate actively with a program that easily measures and tracks progress. Using RMT requires a dedicated team working together with motivated patients to improve outcomes.

As outlined above, engaging patients in specific RMT exercises to strengthen the respiratory muscles has been shown to have significant benefits, including assisting with weaning, strengthening cough, improving swallow function, and improving airway clearance for secretion management. With RMT, the multidisciplinary team can work together, across the continuum of care, to target respiratory muscle strength and improve patient outcomes. Because it is a no-leak Valve, the PMV opens up the possibility of using EMT with this patient population who have tracheostomies and mechanical ventilation and provides future opportunities to study the complementary benefits of using the PMV and RMT together. While there have been studies targeting other specific patient populations, EMT in the patients with tracheostomies has not yet been thoroughly investigated; however, with a closed system, applying the principles of neuroplasticity and the findings from research with other patient populations, the potential benefits for patients with tracheostomies are significant.

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