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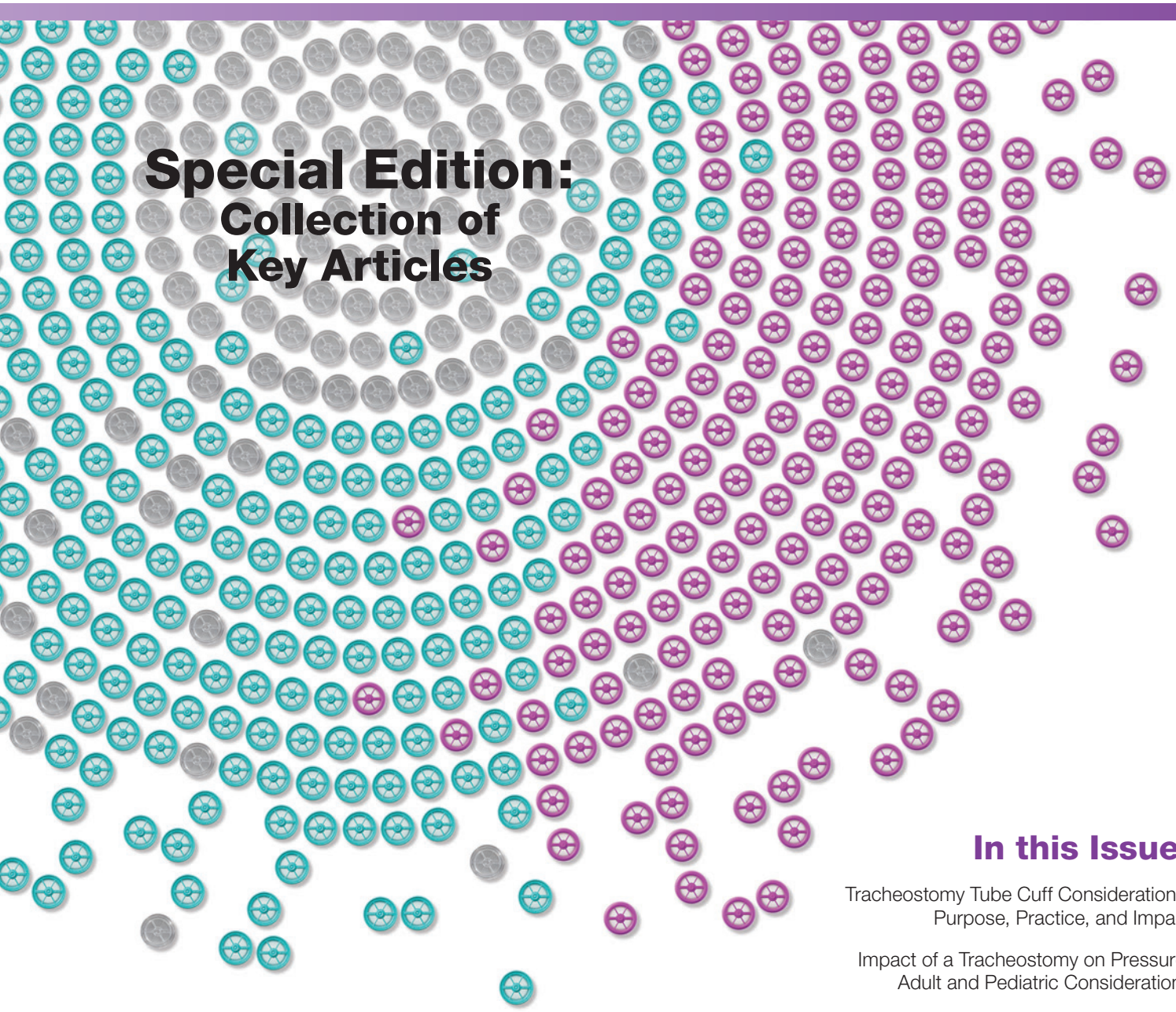

Special Edition:
Collection of Key Articles

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Welcome to Passy-Muir, Inc.'s *Aerodigestive Health*:

Special Edition: Collection of Key Articles

Welcome to this issue of *Aerodigestive Health*. This special collection of articles from past issues features content that contributes key points relevant to clinical knowledge for working with patients with tracheostomies and mechanical ventilation. As we work within the fields of medicine that address the needs of these patients, often healthcare practices are based on physician preference, individual facility policy and procedures, the existence of a trach team, and many other factors. Over the last few years with *Aerodigestive Health*, healthcare professionals have shared their experiences, protocols, and evidence-based practices to enhance the care of patients with tracheostomies and mechanical ventilation. Goals of this publication include disseminating evidence-based practices and working toward a consistent standard of care.

This issue of *Aerodigestive Health* brings together multidisciplinary perspectives that address from in-line use of a speaking Valve. By forming this issue from contributions over the last several years, we offer a wide variety of topics that touch on topics relevant for working with this patient population. The authors include physicians, respiratory therapists (RTs), and speech-language pathologists (SLPs). Their knowledge and skills combine to enlighten the reader on various challenges to overcome. If you are wanting to learn more about patients on mechanical ventilation, then this issue offers support. You also will find an article on the impact of prolonged mechanical ventilation and how SLPs may contribute to the plan of care.

Traditional interventions for patients with other diagnoses are often applied to the patient with a tracheostomy; however, special factors should be considered prior to implementing treatment. In this issue, you will find articles that address assessment and treatment considerations for the pediatric patient, along with specific considerations for adult patients requiring high flow oxygen. Since patients with tracheostomies obviously have compromised respiratory systems, the issue would not be complete without including a comprehensive article on respiratory muscle training.

This publication provides educational and clinically relevant information to enhance the care of patients with tracheostomies, including the safe and efficacious use of the Passy Muir® Tracheostomy & Ventilator Swallowing and Speaking Valve (PMV®). Therefore, it would not be complete without including special contributions on proper cuff management and the impact of a tracheostomy on pressure.

Each of the authors emphasize that multidisciplinary team management is a key element when working with patients of any age following tracheostomy and mechanical ventilation; additionally, the management of an open tracheostomy tube by using a PMV provides multiple benefits that assist with transitioning patients through the levels of care.

Kristin A King PhD, CCC-SLP

About the Editor

Kristin King, PhD, CCC-SLP has been a speech-language pathologist in a variety of settings since 1995. She earned her PhD in Communication Sciences and Disorders from East Carolina University in 2008. Her expertise is in cognitive-communication and swallowing disorders with medically complex patients of all ages, particularly those with needs secondary to traumatic brain injury (TBI), tracheostomy/ventilator, and pre-term birth. Dr. King has published several peer-reviewed articles regarding evaluation and treatment of TBI, and she speaks to both domestic and international audiences regularly on the use of speaking valves, evaluation and treatment following TBI, and swallowing disorders.

Upcoming Issues:

If you have an interest in submitting or writing for one of our upcoming issues, please contact me at ***aerodigest@passymuir.com***.

Tracheostomy Tube Cuff Considerations: Purpose, Practice, and Impact

Michael S. Harrell, BS, RRT | Kristin A. King, PhD, CCC-SLP

Care of patients with tracheostomies has become a frequent topic of discussion in the medical industry and publications. With this focus, details related to the care plan for patients with tracheostomies are of concern and must be considered with a focus on evidence-based and best practice. One significant consideration for patient care is the safety and efficacy of proper cuff management, especially when using a bias-closed position, no- leak Valve.

Purpose of a Cuff

The purpose for having the tracheostomy tube cuff inflated is to direct airflow through the tracheostomy tube and into the lower respiratory system or airway. Use of an inflated cuff occurs typically during mechanical ventilation, as a closed ventilator circuit allows improved control and monitoring of ventilation for the patient. Typically, the patient on a ventilator has a more seriously compromised respiratory system than patients who are not on a ventilator. The inflated cuff assists with a focused management of the support the patient may require.

The inflated cuff also may be important in cases of gross emesis or reflux when gross aspiration is a risk; the cuff may assist in limiting aspirated material entering the lower airway. However, the definition of aspiration is when any food, liquid, or other matter passes below the vocal folds. Therefore, the cuff cannot prevent aspiration as it also is located below the vocal folds (*see Figure 1*). When neither mechanical ventilation nor risk of gross aspiration is present, the cuff should be deflated. If the patient does not need a cuffed tracheostomy tube, transitioning them to a cuffless tracheostomy tube as soon as possible should be a strong consideration.

Practice: Cuff Inflation

The inflated cuff should be avoided whenever possible because it has the potential to cause multiple complications such as: increased risk of tracheal injury, including mucosal injury, stenosis, granulomas, and more; diminished ability to use the upper airway, leading to disuse atrophy over time; and restriction of laryngeal movement (laryngeal tethering) which may impact swallowing negatively. The potential for a negative impact also is affected by the management of the tracheostomy tube cuff, with proper inflation critical to the health of the airway.

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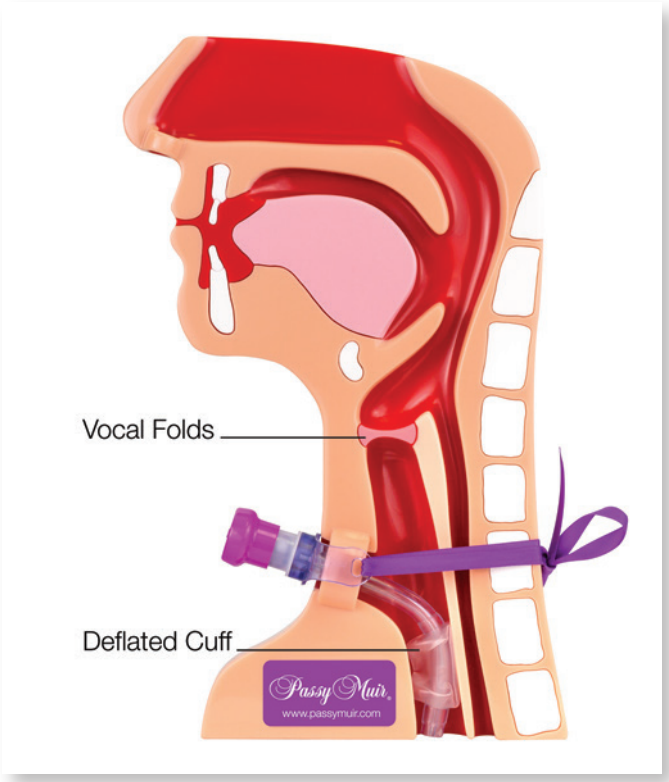

Figure 1. Cuff location in relation to the vocal folds

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If a patient requires an inflated cuff, then the manner in which it is being inflated should be carefully evaluated. The complications that have been reported with tracheostomy tube cuffs may be avoided by ensuring proper management. Three methods which are commonly used to inflate a tracheostomy tube cuff are:

1) Cuff manometer (cuffalator) – the gold standard.
2) Minimal occlusion volume.
3) Minimal leak technique.

While some guidelines provide that cuff pressure should be between 20 – 25 cmH_2O, others suggest 15 – 30 cmH_2O (Credland, 2014). The disparity that exists between resources makes it imperative that healthcare professionals understand the potential impact and how to manage a cuff properly. Using the pilot balloon or pushing air into the cuff by syringe and without a stethoscope places the patient at high risk of an improperly inflated cuff which may cause damage or impairment. Dikeman and Kazandjian (2022) recommended that cuff inflation always occur with the use of manometer or stethoscope.

Practice: Cuff Deflation

Deflating the tracheostomy tube cuff, when appropriate, has been shown to provide many patient benefits, including (Harrell, 2018):

- Reduced risk of potential tracheal mucosal damage.
- Restored physiology, including closing the system by using a bias-closed position, no-leak Valve.
- Restored speech and improved communication.
- Improved swallow.
- Lowered risk of aspiration.
- Earlier rehabilitation.
- Decreased time to decannulation.

Cuff deflation is recognized as an important step in the care plan for a patient with a tracheostomy (Speed & Harding, 2013). The benefits of cuff deflation can be safely and effectively extended to a patient with mechanical ventilation, when appropriate assessment and patient selection is performed (Sutt et al., 2013). This early cuff deflation may improve the time to rehabilitation and potentially avoids the negative consequences related to an inflated cuff. The earlier a patient has their cuff deflated, the earlier the patient may be weaned or decannulated. Even when decannulation is not a goal, cuff deflation may still provide the benefits outlined above on a long-term basis.

Impact of Cuffs on Swallowing

Another reason for closely monitoring tracheostomy tube cuff status is that it may have a negative impact on swallowing. While a consensus does not exist in the research, it has been reported that an inflated cuff may impinge upon swallowing by tethering the larynx and reducing hyolaryngeal excursion during the swallow (Amathieu et al., 2012). Another reported impact is that an over-inflated cuff may impinge on the esophagus, causing reflux of ingested substances. However, research has shown that use of a Passy Muir® Valve improves swallowing and reduces aspiration more often and more significantly than cuff deflation alone (Suiter et al., 2003).

Amathieu et al. (2012) conducted a study looking at incremental increases in cuff pressure for patients with tracheostomies and measured the impact on the swallow reflex. They found that as the cuff pressure increased, the swallow reflex became increasingly more difficult in both latency and magnitude, meaning that the timing and force of the swallow were impacted. Their findings indicated that any pressure above 25 cmH_2O has a significant risk of negatively affecting swallow function. This finding becomes even more significant when considering the role that swallowing function plays in weaning a patient from both mechanical ventilation and from a tracheostomy tube.

A study by Ding and Logemann (2005) investigated swallowing in both cuff inflated and cuff deflated conditions. They found that the frequency of reduced laryngeal elevation and silent aspiration were significantly higher in the cuff-inflated condition as compared to the cuff-deflated condition. Swallow physiology changes also were found to be significantly different among various medical diagnostic categories. The researchers suggested that these findings indicate a need to test both conditions during a swallow study.

In a more recent systematic review, Goff and Patterson (2018) analyzed multiple studies and concluded that patients should be evaluated for possible swallowing impairment regardless of cuff condition. They also suggested that patients should be seen and evaluated on a case-by-case basis to determine the safety of swallowing for return to oral nutrition. These recommendations were suggested because the research to date has not reached a consensus to establish a standard of care for tracheostomy and cuff management as they relate to swallowing.

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Impact of Team Management

The complexity of this patient population lends itself to being managed by a multidisciplinary team (MDT). It has been demonstrated that a team of appropriately trained professionals armed with evidence-based guidelines significantly improves care and reduces negative outcomes for the patient with tracheostomy. A team approach assists with continuous monitoring, proper cuff management, and the patient care plan (Speed & Harding, 2014; deMestral, 2011).

Working with patients following tracheostomy and with mechanical ventilation takes a multidisciplinary team (MDT) approach to ascertain that the needs of the patient are well met. Because of the complex nature of working with these patients, having the involvement of different disciplines provides perspective on various aspects of care. Typically, these patients are followed by both the respiratory therapist (RT) and the speech-language pathologist (SLP). However, many other healthcare professionals are trained and involved with the tracheostomy and use of the Passy Muir® Valve. To initiate an MDT approach, it takes multiple healthcare professionals, including the physician, nursing, dieticians, physical therapists, occupational therapists, and with the patient at the center of it all.

In a study conducted by Fröhlich et al. (2017), the authors investigated best practices for early intervention with use of the Passy Muir Valve as a standard of care in the ICU following tracheostomy and mechanical ventilation. Their findings demonstrated that patients improved with voicing and swallowing more quickly than those without MDT intervention. However, since the authors were able to follow the patients over time, which included up to 51 trials with the PMV, they also reported how the implementation of a team approach had a positive impact on potential adverse events, with none occurring. The researchers attributed this to the multidisciplinary team approach and suggested their findings support the idea that two professionals should be at the bedside to provide assessment and intervention with the PMV in-line with mechanical ventilation.

Santos et al. (2018) also investigated the impact of team management on the post-tracheostomy care of patients. Their findings concur with Frohlich et al. (2017) and suggest that having the involvement of an MDT allows the patient to progress faster in multiple areas. The parameters addressed in their study were time in the ICU, total hospital days, days to Valve use, days to verbal communication, oral intake, and decannulation. The group receiving team management were found to have improved care in all areas measured. Patients who received the Valve with the MDT did so earlier in their care and had voicing, communication, and the ability to participate in their care restored. The positive impact of an MDT on the care of patients and the ability to achieve earlier voicing cannot be overstated in its clinical significance. As with any medical procedure or device, thorough education is important in achieving the desired outcomes.

Summary

It is the responsibility of healthcare professionals to provide the best possible care to their patients. Proper cuff management, including cuff deflation, contributes significantly to the best practice plan of care for the patient with a tracheostomy. Proper cuff management also leads to earlier intervention for communication and swallowing. The safety and efficacy of the plan depends largely on the education and competency of the team caring for these individuals, as well as a commitment from the healthcare facility to a multidisciplinary tracheostomy team approach for patient care.

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Impact of a Tracheostomy on Pressure: Adult and Pediatric Considerations

Kristin A. King, PhD, CCC-SLP

The number of adult and pediatric patients with tracheostomies is growing each year secondary to advancements in medical care and interventions to sustain life more so than seen historically. In a study conducted in 2008, it was estimated that by the year 2020, there would be over 600,000 adult patients requiring prolonged mechanical ventilation (Zilberberg & Shorr, 2008). But little did that author know that, in 2020, a pandemic would change the face of medical care. It was estimated that in 2020, 965,000 people would require mechanical ventilation due to COVID-19, not including other disease and injury processes (Halpern & Tan, 2020). Just considering COVID-19 patients, the potential incidence of tracheostomies is thought to be much higher than the prediction given in 2008.

Aerodigestive changes following tracheostomy

With tracheostomies, changes in the aerodigestive system become evident through impacts on voice, swallowing, cough, and other functions. The prevalence for these aerodigestive challenges, which may lead to feeding and swallowing difficulties, is high.

The placement of a tracheostomy tube and prolonged mechanical ventilation with an inflated cuff causes a disconnect between the upper and lower airway. The lack of airflow through the upper airway can often lead to multiple negative changes affecting speech and swallowing: reduced subglottic pressure (Eibling & Gross, 1996); decreased sensation to the pharynx and glottis (Eibling & Gross, 1996); reduced laryngopharyngeal reflex (Sasaki et al., 1997); decreased ability to manage secretions, requiring more frequent suctioning (Siebens et al., 1993); decreased sense of taste and smell (O'Connor et al., 2019); inability to vocalize; increased aspiration risk; and muscle disuse and atrophy (Griffiths & Jones, 1999). A disconnect between respiration and swallowing also may negatively impact the ability to coordinate breathing and swallowing. For pediatrics, long term tracheostomy placement also has been associated with delayed acquisition of language, delayed social development, and risk of impaired parent-child bonding (Lieu et al., 2013; Cowell et al., 2013).

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A primary means for closing the system to restore more normal physiology and pressures for patients with tracheostomies is the use of a bias-closed position, no-leak Valve. When a patient has a tracheostomy, airflow is directed in and out through the tracheostomy tube and bypasses the upper airway. The Passy Muir® Valve works by closing at the end of inspiration, which redirects 100% of airflow upwards through the vocal cords and upper airway. Research has shown that this redirection of airflow assists with improving secretion management, increasing sensory awareness, improving swallowing, and restoring natural physiologic PEEP (positive end-expiratory pressure), among other benefits (O'Connor et al., 2019).

Normalizing function

Assessment and usage of a Valve also is important for the normalization of functions for all patients and for development in children. The primary consideration during assessment is that the patient has a patent airway, meaning the patient can exhale around the tracheostomy tube. Having a qualified team, familiar with airway management, is a key component of successful Valve use. The participation of infants, toddlers, and young children in the assessment process may be more difficult than with adults because of their limited ability to follow commands and volitionally vocalize; therefore, additional methods, such as transtracheal pressure (TTP) measurements, may be used to assess airway patency (Abraham, 2018). TTP is a method for measuring the pressure in the airway with the tracheostomy tube in place. It can be used with finger occlusion or a speaking valve to determine airway patency. TTP has been found to be a predictor associated with successful use of the Passy Muir Valve (PMV) (Brooks et al., 2020).

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While speech and language development is an important consideration in pediatrics, research from the adult population suggests significant benefits for improved secretion management, cough function, and swallowing, all of which are influenced by pressure (Zilberberg & Shorr, 2008). Research has shown that subglottic pressure is reduced with a tracheostomy, impacting feeding and swallowing, cough, and secretion management (Pullens & Streppel, 2021). Pullens and Streppel (2021) discussed the importance of restoring normal airway physiology to assist with feeding and swallowing, which would include restoring pressure, by using a speaking valve in the pediatric population. The adult population has several studies which indicate the need to restore subglottic pressure to assist with improved laryngeal function, swallow, cough, and secretion management (Zilberberg & Shorr, 2008; Alhashemi et al., 2022).

The negative impact on pressures and the diminished stimulation of sensory receptors may affect feeding and swallowing in the pediatric population, to include oral-motor sensation. Henningfeld, et al. (2019) reported that g-tube feeding and delayed feeding skills were associated with tracheostomy. They also hypothesized that children with tracheostomies would have more feeding issues than their age-matched peers without tracheostomies (Henningfeld et al., 2019). During review, they found that a history of ventilator-dependence, cuffed tracheostomy tube, and speaking valve use during inpatient care were inconsistently associated with later feeding and nutrition evaluations. However, the authors suggested that their findings also indicated that earlier speaking valve use has the potential to decrease later issues with feeding.

Early Assessment Leads to Early Intervention

Early assessment for speaking valve use either in-line with mechanical ventilation or with a spontaneous breather leads to early intervention – in this case, establishing treatment plans, accommodations, and interventions earlier during their care. Early intervention and use of the PMV has been shown to have benefits with restoring the physiology of the upper airway to its more “normal” state by returning airflow through the upper airway during exhalation (Griffiths & Jones, 1997). This restoration of airflow to the upper airway allows evaluation of airway patency, vocal cord function, secretion management, swallowing, and communication skills (Griffiths & Jones, 1997). Research has shown that the use of a Passy Muir Valve can provide benefit during swallowing by increasing laryngeal excursion, returning cough and throat clear, and providing overall improved protection of the airway (Griffiths & Jones, 1997).

Furthermore, patients on mechanical ventilation often experience psychosocial distress related to their inability to communicate with family and caregivers and to participate in their own care. Early implementation of the PMV increases the opportunity for patients to speak, swallow, and participate in direct therapy and to do so sooner. This early intervention has the potential to reduce anxiety, wean times, and lengths of stay. The restoration of communication and restoring oral nutrition have both been shown to have positive psychological benefits and to decrease anxiety, stress, fear, and other negative effects (Freeman-Sanderson et al., 2016).

Whitmore, et al. (2020) also reported that the use of speaking valves for patients with and without mechanical ventilation was highly supported among the reviewed literature to promote speech and communication, which had an additional impact on patient satisfaction, and has been shown also to contribute to alveolar recruitment, weaning, and quality of life (Whitmore et al., 2020). One barrier identified to using measurement tools with patients for assessing pain, cognitive status, and other areas while in the ICU is the ability of the patient to participate verbally (Zaga et al., 2020). Zaga, et al. (2020) identified that the use of a one-way valve in-line with mechanical ventilation would assist with increasing the relevance of some measures (Zaga et al., 2020).

Intrathoracic and intra-abdominal pressures

Additional primary areas of pressure to consider when addressing the needs of patients with tracheostomies are the effects on the respiratory system and intrathoracic and intra-abdominal pressures, which also are diminished by having an open system (Massery, 2014). With the redirection of airflow, the patient is no longer using the upper respiratory airway - airflow does not go through the upper airway and glottis (vocal cords). Use of the upper airway and glottis typically allows for control of exhalation and assists with controlling expiratory lung volumes (Massery et al., 2013). This loss of pressure may impact gross motor function for mobility and postural stability.

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Use of the Valve during physical therapy helps restore the pressure support in the trunk, allowing for natural increases in intrathoracic pressure (ITP) and intra-abdominal pressures (IAP) in response to increased postural demands. With an open tracheostomy tube and therefore, an open system, thoracic pressures cannot be increased or sustained as airflow passes through the tracheostomy tube and bypasses the upper airway. This difficulty would be observed when a patient needs to crawl, sit, push, or stand up. The typical means of gross motor movement for mobility is to engage the glottis (vocal cords) to restrict the expiratory lung volume to stabilize the chest and upper body (Griffiths & Jones, 1997; Cowell et al., 2013). Placing a Passy Muir Valve on the tracheostomy tube closes the system and restores a patient's ability to use the upper airway to control expiratory flow and improve ITP and IAP.

Consider that with infants and young children, a tracheostomy also could limit or diminish gross motor development. During infancy and early development, children are progressing through the stages of head control, trunk control, sitting, reaching, standing, and walking. Without good ITP and ITA, these functions could be significantly impacted and even delayed. A vicious cycle may begin as fine motor skills related to feeding, self-feeding, and other levels of function are directly linked to gross motor development. These delays and limitations can be mitigated by using a Passy Muir Valve to return the young child to a more normalized use of the upper airway with control of volumes and improved trunk control and postural stability. For adults, restoring pressure improves and restores functions that aid in recovery and quality of life.

Conclusion

The provision of multiple services for these patients with tracheostomies assists with overall care and recovery. Having these patients receive intervention to restore communication and swallowing, improves overall mental health which in turn impacts motivation and recovery (Lieu et al., 1999). Taking into consideration the impacts disease processes and intubation or tracheostomies have on communication and swallowing, early assessments may be a key component to restoring patients' abilities to communicate, eat, and return to more normal function, no matter the age.

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Speaking Valve Use During Mechanical Ventilation: More than Just for Communication and Swallowing

A Respiratory Therapist's Perspective

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The inability to communicate during periods of mechanical ventilation (MV) can increase psycho-emotional distress (Egbers, et al., 2014) and has been associated with depression and post-traumatic stress disorder (Freeman -Sanderson, et al., 2016). One way speaking valves can be used to restore verbal communication for patients who require MV. The Passy Muir® Valve is the only bias-closed position valve that can be used during MV. The Passy Muir Valve opens during inspiration and closes at the end of inspiration, re-directing exhalation through the vocal cords and out through the mouth and nose, which allows for verbal communication. The restoration of airflow, sensation, and positive airway pressure to the aerodigestive tract returns the upper airway to a more normal physiologic condition and may also have other clinical benefits for the patient who requires tracheostomy and MV.

It is common to delay intervention by speech-language pathologists and the use of speaking valves in the ICU on patients who require mechanical ventilation, based on the rationale that patients are "too sick." The literature suggests that this hands-off approach may cause more harm than good and early intervention can minimize or potentially reverse the impact (Burkhead, 2011). The Speech-Language Pathologist (SLP)-Respiratory Care Practitioner (RCP) team is presented with a unique opportunity to co-treat patients who require tracheostomy and MV to provide not only a way to communicate, but a way to restore airflow and engage the glottis and restore positive pressure to the aerodigestive tract. This therapy may enhance weaning and rehabilitation including safer swallowing to reduce aspiration (Amathieu et al., 2012; Rodrigues et al., 2015), improve swallow and cough (Pitts et al., 2009), reduce respiratory infections (Carmona et al., 2015), promote alveolar recruitment (Sutt et al., 2015) and enhance early mobilization efforts (Massery, 2014).

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With few exceptions, patients who require tracheotomy were previously intubated. The presence of an endotracheal tube, along with infection, medications, immobility, disuse atrophy, and co-morbidities often lead to ICU acquired muscle weakness. Muscle weakness is a factor in dysphagia and is associated with increased symptomatic aspiration risk leading to significant morbidity and mortality in ICU patients (Mirzakhani et al., 2013). Lack of airflow to the upper airway during endotracheal intubation continues after a tracheostomy tube is placed with inflated cuff and can lead to sensory changes in the mucosa of the oropharynx and larynx contributing to dysphagia (Burkhead, 2011). A significant number of these patients also develop diaphragmatic weakness as well, resulting in significantly longer duration of MV (Supinski & Callahan, 2012). Diaphragmatic force generating capacity may be reduced as much as 32% after just 5 or 6 days of MV (Schellekens et al., 2016). Respiratory weakness is often associated with difficult weaning and increased mortality. Therefore, it would be reasonable to consider Respiratory Muscle Training (RMT) as part of the weaning and rehab process, along with consideration for preventative strategies to reduce or slow disuse atrophy of the respiratory muscles (Schellekens et al., 2016). RMT has also been linked to improved swallow and cough (Pitts et al., 2009). RMT is generally defined as a technique for improving respiratory muscle function and includes performing inspiratory and/or expiratory maneuvers against a resistance. However, further research is needed to

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establish efficacy in certain patient groups and specific training protocols should be implemented for Respiratory Muscle Training specific to various patient populations. Inspiratory Muscle Training (IMT) has been reported to increase exercise endurance, muscle strength, and perceived dyspnea in patients with COPD (Geddes et al., 2008), and Expiratory Muscle Training (EMT) has been linked to reduced perception of dyspnea in COPD patients during exercise and improved cough and swallow safety (Laciuga et al., 2014).

While patients with tracheostomy and MV participate in a weaning and rehabilitation process, they also must have their communication needs met. Clinicians would agree that patients may be able to employ different methods of verbal communication at varying times during their illness, and any and all methods of providing voicing should be explored. However, while some methods of ventilator assisted speech do assist the patient with voicing and the ability to communicate (McGrath et al., 2003), they do little to restore upper airway physiology to a more normal condition.

Some have suggested that partial cuff deflation during MV is a preferred means to accomplish speech; however, while this may be useful in a select group of patients who are unable to manage full cuff deflation, it may not be the best way to restore upper airway physiology. It was suggested by Hoit et al., (2003) that the combination of increasing inspiratory time and increasing PEEP, as high as 15 cmH_20 in some subjects, produced a quality of voicing identical to using a speaking valve. The author also stated that "high PEEP is a safer alternative than a one-way speaking valve" (Hoit et al., 2003). However, it may be more likely that the subjects were performing high flow leak speech. High inspiratory flows, along with increased PEEP, may be difficult for weak patients to manage, leading to increased work of breathing, and/or breath stacking. It should be noted the authors did not have findings within the study to support the claim of improved safety with this method. In addition, encouraging speech while the ventilator is delivering an inspiratory breath is not natural speech, as natural voicing occurs during the expiratory cycle.

McGrath et al. (2016) proposed an alternative method of ventilator assisted communication by using a tracheostomy tube with a subglottic suction port. The port is used to deliver a low flow of gas above the cuff, which may be inflated or partially deflated. The reported limitations to this method include limited voice quality, possible laryngeal injury with higher flows, stoma leakage of gas, and the dry gas delivery causing drying of the mucosa and hyper-adduction of the vocal folds (McGrath et al., 2016). While this method has its drawbacks, it may be a good alternative for the ICU patient who is too sick or unable to manage cuff deflation even for short periods of time. However, another consideration is that this is a specialized trach and may require a trach change for the patient.

While therapies like RMT assist with improving coughing, swallowing, and trunk strength, tasks such as walking, balance and exercise require engaging the glottis and airflow to the upper airway (Massery, 2014). Normalized voicing also requires engagement of the glottis and airflow through the upper airway. To achieve this engagement, the cuff must be completely deflated and a no-leak speaking valve placed on the tracheostomy tube to allow for 100% of exhalation to flow through the glottis, upper airway, mouth and nose. It is also important to understand how to maintain adequate ventilation with the cuff of the tracheostomy tube deflated. A thorough upper airway assessment to assure upper airway patency must be performed prior to use of a no-leak speaking valve. Some practitioners may be hesitant to try managing MV in the cuff deflation condition, concerned that adequate ventilation cannot be maintained. In a study done on "unweanable" ventilator dependent patients with neuromuscular disease, Bach reported that 91 out of 104 patients were adequately ventilated with either the cuff deflated or with cuffless tracheostomy tubes (Bach & Alba, 1990).

One way speaking valves have long been used to allow for airflow through the upper airway for speech. Clinicians should consider the other possible benefits…

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The most likely patient to manage cuff deflation is one who is medically stable, awake, and engages the voice. It might be appropriate to begin cuff deflation sessions in conjunction with sedation vacations (when sedating medications are not being used). The clinician should understand that a patient who has not felt airflow through the upper airway for several weeks, or even longer, may not achieve full cuff deflation in one session. Some ventilator adjustments that may make cuff deflation more successful include reducing or eliminating PEEP and/or changing sensitivity settings, so that the ventilator does not auto cycle. Sutt et al. (2016) reported improved lung recruitment when using the Passy Muir Valve in conjunction with MV with the PEEP reduced or turned to zero. This improvement was maintained for a period of time, even after the one-way valve was removed. The authors attribute this maintenance to the return of a more normal upper airway resistance since exhalation occurred through the larynx and upper airway. At this stage of assessment, it is very important for the SLP and RCP to work closely together and employ strategies to assist the patient in maintaining adequate ventilation. The RCP will manage the ventilator alarms and monitor ventilation, while the SLP can cue the patient to breathe in during the inspiratory cycle of the ventilator and perform an expiratory maneuver to trigger the ventilator into exhalation in the presence of the leak during cuff deflation. This coordination with the ventilator is then transitioned to coordinating respirations with voicing on exhalation and may lead to coordinating respirations and swallowing. In addition to ventilator adjustments, the process of cuff deflation should not be rushed. Some patients will take longer to manage this step due to weakness of the laryngeal and pharyngeal muscles/structures and reduced sensation. A patient may exhibit coughing, throat clearing, shortness of breath, and other signs of adjustment – all of which are a part of the process in learning to coordinate breathing with the ventilator and developing a sense of normalcy with a return of airflow through the upper airway. Additionally, good oral care and suctioning as needed are important before and during this step of the airway assessment.

Once the cuff is completely deflated, airway patency can be determined by assessing voicing on exhalation, listening for exhalation though the upper airway using a stethoscope, or by reading the peak inspiratory pressure (PIP) and/or exhaled volumes via the ventilator. The clinician can objectively document an adequate leak and upper airway patency when reading a 40-50 percent drop in PIP and/or decrease in exhaled tidal volume measured by the ventilator. These measurements would suggest that the tracheostomy tube is properly sized to allow for sufficient airflow around the tracheostomy and upwards to the upper airway. It also suggests that there is no significant obstruction above the tracheostomy tube. A no-leak speaking valve then can be placed into the ventilator circuit while mechanical ventilation continues.

Once the no-leak valve has been placed in the ventilator circuit, the RCP and SLP continue to work together to assure patient-ventilator synchrony and adequate ventilation. The SLP may provide inspiratory and expiratory cues to the patient while the RCP monitors ventilation by monitoring PIP. PIP should be closely monitored since it is the measure of adequate ventilation comparable to pre-cuff deflation and no exhaled air will return or be measured by the ventilator. It may be necessary to increase delivered volume to achieve pre-cuff deflation PIP and assure adequate alveolar ventilation; however, this step may not be needed once the patient gets stronger. At this stage, the RCP should manage the ventilator alarm settings following safe practice. Other vent specific strategies may also be utilized depending on the mode of ventilation or brand, including flow or time limiting pressure delivered breaths and consider whether it is appropriate to use leak compensation as provided by the specific ventilator.

As the aerodigestive system is returned to the more normal condition with the use of a Passy Muir Valve in-line with MV, therapies that require glottis engagement, positive sub-glottic pressure, and airflow can begin. As previously mentioned, oral intubation and reduced airflow to the airway may result in decreased sensation, in addition to disuse atrophy and muscle weakness (Mirzakhani et al., 2013). Individualized therapeutic programs may be developed, requiring that therapies be modified for each patient dependent on the level of function. Progress may be slow in some patients with multiple co-morbidities but should be pursued when medically appropriate to ameliorate deterioration as much as possible.

One way speaking valves have long been used to allow for airflow through the upper airway for speech. Clinicians should consider the other possible benefits to the patient when airflow, sensation, and positive pressure is restored to the upper airway as part of the weaning strategy for patients who require MV. Use of a Passy Muir Valve during MV also provides improved access for treatment of dysphagia and increases participation in physical therapy through improved

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trunk stability and postural control, which may lead to improved weaning rates, reduced time of MV, and shortened ICU length of stays. According to Grosu et al. (2012), ("Difficulties in discontinuing MV are encountered in 20% to 25% of patients who receive MV, with a staggering 40% of the time spent in the ICU devoted to weaning from MV. Hence, techniques that expedite the weaning process should have a profound effect on the overall duration of MV.") Clinicians should consider cuff deflation and speaking valve trials early in the process of weaning – not only to enhance quality of life by allowing the patient to have a voice, but to provide the benefits of restored physiology and the potential positive impact on weaning.

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Tips for Ventilator Application | Sudderth

Effects Of:

Cuff Inflation	Reduced Upper Airway Stimulation	Reduced Positive Airway Pressure	Tracheostomy
Reduced Laryngeal Movement/ Tethering	Loss of Voice	Reduced Swallow Function	Quality of Life
Necrosis/ Trauma	Reduced/ Lost Taste and Smell	Weak or No Cough	Weaning
Reflux	Change in Sensation	Reduced Trunk Strength/ Support	Length of Stay
Reduced Upper Airway Airflow	Negative Impact on Swallowing	Reduced PEEP	

Tips For Ventilator Application

Monitor PIP and EVT to assess upper airway patency during deflation

Slow cuff deflation, with frequent oral care and suctioning as needed

Make ventilator adjustments to improve cuff deflation management

Consider:

- Decreasing PEEP
- Increasing Vt in increments of 50-100 to return to pre-PMV PIP

Assure adequate alveolar ventilation by monitoring PIP and WOB

Use safe alarm practice

Understanding the Management of Patients Undergoing Prolonged Weaning from Mechanical Ventilation: Perspectives from a Speech-Language Pathologist and a Respiratory Physician

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Patients presenting with respiratory failure are now surviving with the help of medical advances, including tracheostomy tubes and mechanical ventilation. The care of patients on mechanical ventilation has changed significantly over recent decades. Since the 1950s, there has been a shift from devices delivering negative-pressure mechanical ventilation to invasive positive pressure ventilation modes. Frequently, ventilation is delivered via tracheostomy tubes and permits prolonged mechanical respiratory support for most individuals with respiratory failure. The presence of the tracheostomy tube accomplishes multiple airway management goals; establishing a patent airway, as well as providing a connection to assisted ventilation (Robert & Argaud, 2007).

A uniform and broadly accepted definition of the term "weaning" is crucial to avoid confusion and is an essential prerequisite for interpreting the literature and guiding clinical decision-making. Weaning from mechanical ventilation is defined as "the process of withdrawing ventilator support" (Navalesi et al., 2014). It is commonly accepted that the process of weaning starts with the first spontaneous breathing trial (SBT), during which the patient is allowed to breathe for a relatively brief period of time (30–120 min) through a T-tube, or with low levels of either CPAP (2–5 cmH_2O) or pressure support (≤ 8cmH_2O). When the SBT is successful, the patient is considered weaned and ready to be extubated, provided that the natural airway is not at risk for obstruction.

A recently proposed and largely accepted classification based on the difficulty and duration of the weaning process includes: (1) simple weaning, i.e., the patient passes the initial SBT and is successfully extubated at the first attempt; (2) difficult weaning, i.e., up to three SBT or 7 days from the first SBT are necessary to withdraw mechanical ventilation and extubate the patient; (3) prolonged weaning, i.e., more than three SBTs or 7 days from the first SBT are required (Boles et al., 2007).

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The variability of the potential influences on weaning success has created awareness that the process is facilitated by a "best practice" of collaborative multidisciplinary care. O'Bryan et al. (2002) described weaning protocols for a system of long-term acute care hospitals that included a consistent approach and protocol to weaning, the participation of rehabilitation services, and early and aggressive intervention as well as nutritional support. There is evidence that implementing standardized weaning protocols may reduce the duration of mechanical ventilation and length of stay in the Intensive Care Unit (ICU) patients (Blackwood et al., 2011). However, it is important that when applied specifically to the subset of patients with weaning difficulty, the use of "weaning protocols" are tailored to the individual patient, reflecting a holistic, multidisciplinary assessment, including consideration for the underlying cause and aggravating factors contributing to prolonged mechanical ventilation.

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In the ICU, the majority of patients can be successfully liberated from mechanical ventilation without difficulty (Cohen & Booth 1994). However, up to 50% of the time a patient spends on the ventilator may be involved in the process of weaning from mechanical ventilation and approximately 14% of patients receiving mechanical ventilation undergo a "prolonged weaning" process (Esteban et al., 1994; Funk et al., 2010).

The Burden of Prolonged Weaning

A report from the UK revealed that 8% of ICU patients had "weaning delay" (defined as the need for ventilatory support for more than 2 weeks in the absence of any non-respiratory factor preventing weaning) and 7% had so-called "weaning failure" (if this state persisted for 3 weeks or more) (NHS Modernisation Agency, 2002). While for approximately 70% of patients, the weaning process is simple and successful; for the remaining 30%, the initial attempt fails, making the weaning difficult and worsening prognosis. ICU mortality has been reported to be as high as 25% in these patients, with about half progressing to prolonged weaning (Navalesi et al., 2014). Furthermore, patients with prolonged weaning account for 6% of all ventilated patients but consume 37% of ICU resources (Warren et al., 2003). From an economic perspective, US annual costs for mechanical ventilation are estimated to be 27 billion dollars, corresponding to more than 10% of all hospital costs. Each year, about 300,000 people receive prolonged mechanical ventilation in ICU's in the US, and this number might double within the next decade, with costs increasing up 50 billion dollars (Zilberburg, 2008). Therefore, prolonged weaning carries not only a medical but also a significant social and economic burden.

The Role of Specialized Weaning Units and Multidisciplinary Teams

The appropriateness of the ICU environment for long-term management of patients undergoing prolonged weaning may be questioned by the detrimental consequences on the psychological and cognitive function of these patients, coupled with a paucity of ICU beds failing to adequately address demand. An otherwise stable patient who remains on mechanical ventilation may be considered for transfer to a specialized weaning unit (SWU). Though there is not a precise definition, SWU can be considered as highly specialized and protected environments for patients requiring mechanical ventilation despite resolution of the acute disorder. The philosophy of such units lies in the delivery of holistic care from a truly multidisciplinary team encompassing a variety of specialties, including skilled nursing staff, physiotherapists (a designation used outside the US; within the US, the team would have respiratory therapists and physical therapists), physicians, speech-language pathologists, dieticians, psychologists, mental health services, social workers and palliative care.

Such an approach to "difficult weaning" would include an appreciation of the existence of underlying medical and psychological problems that may be contributing to weaning delay in each patient that may have been unrecognized in a busy ICU setting. These include the presence of chronic hypoventilation (failure to breathe rapidly enough or deeply enough), parenchymal lung disease (a group of lung diseases affecting the interstitium (the tissue and space around the air sacs of the lungs), neuromuscular conditions, cardiac disease, electrolyte abnormalities, nutritional deficiencies, inadequate muscle mass, and significant critical illness neuropathy. The tenets of care in specialized weaning units aim to focus on privacy, sleep quality, utilization of weaning protocols tailored to the individual patient, and optimizing comorbid medical conditions in an environment away from an acute ICU with the absence of invasive monitoring or multi-organ support (NHS Modernisation Agency, 2002).

To highlight the benefits of such an approach, a prospective study of 262 patients receiving prolonged invasive mechanical ventilation admitted to one such specialized unit in the UK over an 8-year period reported a successful outcome from weaning (i.e. liberation from invasive ventilation) in 64% of the patients (Mifsud Bonnici et al., 2016). Of those who were successfully weaned, 62% of those participants discharged were alive 12 months post discharge. Other observational studies report that 34–60% of patients in specialized weaning units can be weaned successfully from ventilatory support and suggest successful weaning can occur up to three months after admission to these SWU's, without adversely affecting long-term mortality (Boles et al., 2007).

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Initial Strategies for Patients Undergoing Prolonged Weaning

A preferred initial strategy is to maintain mechanical ventilation completely at nighttime; therefore, ensuring the patient has adequate "rest" during this period whilst aiming for either progressive ventilatory independence or a gradual reduction in the level of ventilator support in the daytime, depending on the individual patient. This initial approach is supplemented by regular detailed review of the patient's swallow and bulbar function. When possible, progressive periods of tracheostomy cuff deflation during the daytime and allowing the patient to talk through speech devices, such as the Passy Muir® Tracheostomy & Ventilator Swallowing and Speaking Valve, are utilized. Allowing the patient to talk, regaining the sensation of taste and resuming oral, nutritional intake as early as feasible during the weaning process, carries significant physical and psychological benefits. The tracheostomy may also be downsized permitting the introduction of Non-Invasive Ventilation (NIV) early in the weaning process, if deemed safe and appropriate; still enabling the patient to receive ventilation by tracheostomy, if required. It is also imperative to ensure that aggressive secretion management occurs in patients, if successful liberation from tracheostomy ventilation is to occur.

Non-Invasive Ventilation

The application of NIV in subjects with weaning difficulty has been shown in the literature to represent a useful strategy (Burns et al., 2013; Girault et al., 2011). Ferrer et al. (2003) investigated the use of NIV in weaning by randomizing 43 participants undergoing invasive mechanical ventilation who had failed a 2-hour T-piece trial for 3 consecutive days to either extubating and NIV or a "conventional" weaning plan consisting of continued daily weaning attempts. Liberation from invasive ventilation and 90-day survival were both greater in the NIV arm, where there was a significantly decreased incidence of nosocomial pneumonia and septic shock. A randomized controlled trial conducted in 13 ICUs comprised of 208 participants with chronic hypercapnic respiratory failure (respiratory failure with increased arterial carbon dioxide levels), who had failed an SBT, found that the group who was extubated to NIV had a significantly reduced occurrence of acute respiratory failure post-extubation compared to those extubated to oxygen therapy or those who continued a weaning strategy using Intermittent Mandatory Ventilation (IMV) (Girault et al., 2011). The results from these studies suggest that NIV represents a useful tool in the management of patients undergoing a prolonged weaning process.

High Flow Nasal Oxygen Therapy

Another technique that has a potentially useful application in the weaning process is that of High Flow Nasal Oxygen Therapy (HFNOT). HFNOT aims to derive greater physiological benefit by delivering heated and humidified oxygen therapy through a nasal cannula at higher flow rates (up to 60 liters/minute) when compared to standard oxygen delivery devices (Spoletini et al., 2015). This results in greater washout of the upper airway dead space facilitating removal of carbon dioxide. It also results in delivery of a small degree of Positive End Expiratory Pressure (PEEP), allowing alveolar recruitment, thus aiming to reduce the work of breathing as well as maintaining patient comfort through the delivery of warm humidified gas. At present, there is a paucity of high-quality evidence examining the utility of HFNOT in subjects undergoing prolonged weaning despite some data pointing to improvements in oxygenation with HFNOT in this cohort (Corley et al., 2017). In a multi-center study comparing 604 extubated patients deemed at high risk of re-intubation randomized to either HFNOT or NIV post-extubation, no significant differences were noted in the rate of re-intubation or in-hospital mortality (Hernandez et al., 2016). Whilst such data is encouraging, further research is needed in this area to identify those subgroups of patients with weaning difficulty who may benefit from the use of HFNOT as a tool in the liberation from mechanical ventilation.

Management of Comorbidities

Adequate management of comorbidity also is integral to the management of patients with weaning difficulties. For example, it is important that healthcare professionals pay attention to fluid overload and to the optimization of cardiac function during the weaning process. A weaning strategy that includes fluid management driven by serum B-type natriuretic peptide (BNP) levels has been shown to confer superior outcomes in terms of duration of weaning and time to successful extubation when compared to a more conventional approach with no significant differences in terms of incidence of electrolyte abnormalities and renal failure between the two groups. A potential mechanism postulated to explain the beneficial outcomes reported of such a biomarker based approach may lie in the reduction of Ventilator Associated Pneumonia (VAP) as pulmonary edema may affect the alveolar bacterial clearance (Mekonto Dessap et al., 2014).

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Role of Allied Health Professionals and Trach Teams

The role of physical therapy and occupational therapy at an early stage in the management of patients aiming to be liberated from mechanical ventilation cannot be over-emphasized. Early physical and occupational therapy is feasible from the onset of mechanical ventilation, despite high illness acuity and presence of life support devices. Adverse events are uncommon, even in this high-risk group (Pohlman et al., 2010). This includes multiple domains such as early mobilization and transferring, attention to posture and balance, maintenance of muscle mass, peripheral muscle training, airway secretion management, and respiratory muscle training (Ambrosino et al., 2012). To emphasize the importance of rehabilitation, the "real world" service review reported that 48.1% of patients admitted to a specialist weaning unit in the UK were discharged to the referring hospital for on-going rehabilitation needs (Mifsud Bonnici et al., 2015).

Another area of utmost importance in the management of subjects with weaning difficulty is the role of Clinical Psychology and Mental Health services. The impact of prolonged mechanical ventilation and the events leading to the ICU admission may carry a significant burden both on patients and family members in terms of depression, anxiety, and other mental health issues and this may be overlooked by healthcare professionals in a busy ICU environment. In a seminal study, depressive disorders were found to be present in 42% of patients undergoing weaning difficulty and were associated both with weaning failure and an elevated mortality rate (Jubran et al., 2010b). These issues may persist even after the weaning period; highlighting the importance of creating a structured holistic follow-up program for patients following discharge from the hospital. Beyond healthcare professionals simply recognizing such conditions, it is worth appreciating that such a traumatic experience may greatly alter the patient's perception of the environment around them, their progress during the process of being liberated from the ventilator, medical interventions and actions of healthcare professionals caring for them. Nutritional status is integral in the weaning process. Patients with tracheostomy who are dependent on ventilators, and who have decreased nutritional intake, may experience protein–calorie malnutrition, which reduces respiratory muscle strength and function. Registered Dieticians play an integral part in the nutritional management of such patients. Through special enteral feeding formulas and oral supplements, dieticians can address hypoalbuminemia (low level of albumin in the body) and heal and prevent pressure ulcers, while maintaining optimal support for weaning. When an oral diet is recommended, Speech-Language Pathologists and Registered Dieticians work closely together to maximize caloric intake, modifying consistencies as needed to achieve appropriate nutrition and hydration in the safest and most effective manner.

Placement of a tracheostomy tube may be necessary for patients in the ICU with respiratory failure. In fact, the incidence of tracheostomy seems to be increasing out of proportion to the increased need for mechanical ventilation. This has led some hospitals to develop specialized tracheostomy teams to standardize and deliver specialized patient care to reduce perioperative tracheostomy-related complications; typically delivered by multiple providers, including the primary physician, resident, mid-level providers, consulting surgeon, nurse, Respiratory Therapist, and Speech-Language Pathologist. Multidisciplinary tracheostomy and wean teams have been successful in improving patient outcomes. One study showed that the addition of a post-tracheostomy care bundle to a multidisciplinary tracheostomy service significantly improved rates of decannulation and tolerance of oral diet (Mah et al., 2016). Standardized care provided by a specialized multidisciplinary tracheostomy team also was associated with fewer tracheostomy-related complications and an increase in the use of speaking valves (Mah et al., 2016).

Role of the Speech-Language Pathologist (SLP) in Patients Undergoing Prolonged Weaning

Speech-Language Pathologists (SLPs) address the communication and swallowing needs of the tracheostomized and ventilator-dependent population throughout the course of the patient's recovery. Adults who are tracheotomy and ventilator dependent or who are undergoing prolonged weaning are some of the most challenging patients in the caseload of an SLP. Airway issues influence many aspects of patient care, including swallowing. The medical issues for patients with these complex cases greatly affect their rehabilitation. Physicians, SLPs, and other members of the multidisciplinary team must work together in their management, especially to understand the influence of pulmonary physiology on swallowing and swallowing dysfunction. Often, these tracheostomized and ventilator dependent patients have long-term alternative feeding methods placed early in their acute medical course. Without SLP intervention, these patients may never return to an oral diet. Communication and swallowing management can greatly enhance the quality of life for these long-term mechanically ventilated individuals.

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Swallowing

Deglutition and respiration are shared systems. Remediation of swallowing function can assist in the weaning and decannulation process by restoring airflow to the upper airway and addressing airway protection deficits. The entire medical team must have an appreciation for the timing of swallowing management with other medical interventions, such as weaning, and make appropriate adjustments to the patient's plan of care. For those individuals where weaning from mechanical ventilation is not possible, the ability to take even a small amount of oral intake can greatly improve their quality of life (Dikeman & Kazandjian, 2000). The clinical literature does not support a direct, causal relationship between tracheostomy, mechanical ventilation, and swallowing impairment; however, the clinical course of these medically fragile patients typically includes a disruption of swallowing function (Donzelli et al., 2005). Many of these patients receive feeding tubes simultaneously with the tracheotomy, without a swallow assessment. This may result in the patient's long-term non-oral status, influencing an important aspect of quality of life. For some individuals, the events that led to respiratory failure and the need for mechanical ventilation may create dysphagia or exacerbate dysphagia that is already present. In addition, the presence of dysphagia may affect the individual's ability to wean from ventilation. The consequences of pulmonary aspiration may be more significant for patients already in an immuno-compromised state, who are often malnourished, have multiple medical issues, and are receiving polypharmacy (Langmore, 1996).

Communication

This is a key issue for ventilated patients, who find the inability to speak distressing (Dikeman et al., 2000). Difficulties with communication in the tracheostomy patient population have been associated with social withdrawal, leading to depression, lack of motivation to participate in care (Leder, 1990; Freeman-Sanderson et al., 2016), poor sleep, and increased anxiety and stress levels (Egbers, 2014; Freeman-Sanderson et al., 2016) which have both short-term and long-term impacts on patient outcomes in ICU and post ICU stays. By demonstrating the potential physiological benefits on top of the already known and more obvious psychological benefits, speaking valves present an excellent way to improve patient care in the ICU.

Use of Speaking Valves

The inability to communicate during periods of mechanical ventilation (MV) can significantly increase psycho-emotional distress (Egbers et al., 2014) and has been associated with depression and post-traumatic stress disorder (Jubran et al., 2010a). One-way speaking valves can be used to restore verbal communication for patients who require MV. The Passy Muir Valve is the only bias-closed position valve that can be used during MV. The Passy Muir Valve opens during inspiration and closes at the end of inspiration, re-directing exhalation through the vocal cords and out through the mouth and nose, which allows for verbal communication. The restoration of airflow, sensation, and positive airway pressure to the aerodigestive tract returns the upper airway to a more normal physiologic condition and may also have other clinical benefits for the patient who requires tracheostomy and MV. Speaking valves can be used in-line with mechanical ventilation but use of these requires deflation of the tracheostomy cuff.

It is not uncommon, however, for the SLP to meet resistance when requesting cuff deflation. There is still the misconception that the cuff prevents aspiration. There is also a fear that adequate ventilation cannot be achieved. The SLP can provide education and evidence to alleviate these concerns. It has been demonstrated that ventilation and stable respiratory parameters can be achieved with the cuff fully deflated and with placement of a Passy Muir Valve. Most recently, clinicians in a cardiothoracic ICU were able to reveal that deflating the cuff and using the Passy Muir Valve increased end expiratory lung impedance, therefore serving as a lung recruitment intervention (Sutt & Fraser, 2015). Due to these findings, use of Passy Muir Valves with ventilator patients increased from 0% to 70% and is now the standard of care in that ICU.

It has been demonstrated that ventilation and stable respiratory parameters can be achieved with the cuff fully deflated and with placement of a Passy Muir® Valve.

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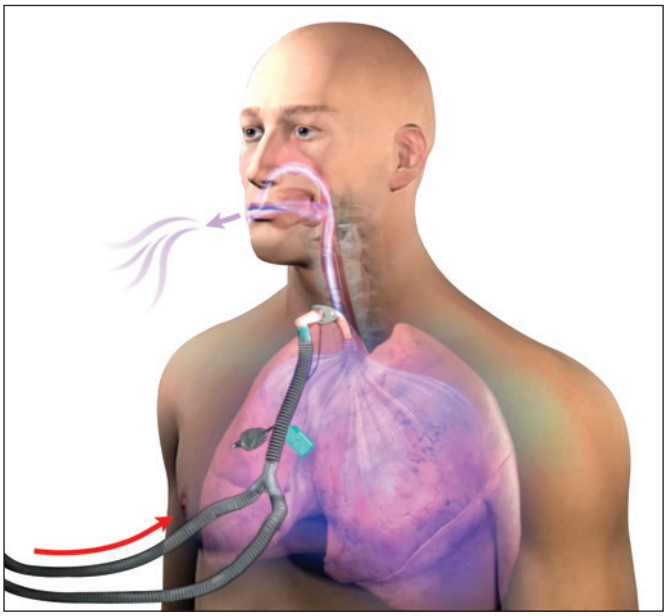
The SLP must work closely with the Respiratory Care Practitioner (RCP) and Respiratory Therapists (RTs) to understand how particular ventilator settings and the level of patient control of breathing may impact the patient's ability to synchronize breathing and swallowing. Using the Passy Muir Valve in-line may require ventilator adjustments to assure patient comfort, safety, adequate ventilation and ability of the patient to perform speech and swallow tasks. These adjustments are made by the RCP/RT trained in such procedures under the guidance of the physician. For the ventilated patient, the team determines the roles of the RCP and SLP as related to cuff deflation and placement of the Valve in-line with the ventilator circuitry. The RCP typically is responsible for procedures such as downsizing the tracheostomy tube and adjustments to the ventilator settings as stipulated in the facility's Policy and Procedures.

Therefore, the SLP-RCP team is presented with a unique opportunity to co-treat patients who require tracheostomy ventilation to provide not only a way to communicate, but also to restore airflow and engage the glottis, restore positive pressure to the aerodigestive tract, and address rehabilitation of the aerodigestive system as needed. This therapy may enhance weaning and rehabilitation by promoting safer swallowing to reduce aspiration, improved swallow and cough (Pitts, et al., 2009), reducing respiratory infections, promoting alveolar recruitment (Sutt et al., 2015,) and by enhancing early mobilization efforts (Mah et al., 2016).

Conclusion

In summary, prolonged weaning from mechanical ventilation constitutes a significant burden in terms of morbidity and mortality in the ICU. Successful liberation of such patients from mechanical ventilation lies in availing a multidisciplinary approach to care in any setting, developing specialist weaning units, and following standard weaning protocols. When working with patients who are being weaned from mechanical ventilation, clinicians must appreciate the interaction between respiration, swallowing, and communication systems. Impairment in these systems is closely linked; and in conjunction with other comorbidities of chronic illness, such as recurrent infections and decreased nutrition, the ventilator weaning process is often challenging. Multidisciplinary teams must work together to facilitate patient recovery and liberation from mechanical ventilation.



No-leak Valve in-line with mechancial ventilation

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Using the Passy Muir® Valve in

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Our facility, Madonna Rehabilitation Hospitals, utilizes warm mist humidification during the care of patients with tracheostomy. As innovation is one of the facility's core values, the Vapotherm Precision Flow device for High Flow Oxygen Therapy (HFOT) was introduced at Madonna in January 2016. This technology allows for delivery of gas flow rates of up to 40 LPM (liters per minute) without discomfort or damage to airway epithelia (Lindenauer et al., 2014). Key clinical benefits of the Vapotherm Precision Flow device include:

- Humidification at body temperature and saturated – 37°C.
- Delivering consistent, energetically stable, vapor phase humidity.
- Rainout prevention.
- Mitigation of contamination via humidity.
- Mitigation of stoma irritation.
- Better secretion mobilization.

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Conjunction with High Flow Oxygen Therapy

A comparison of HFOT and low flow O_2 (oxygen) demonstrates that:

	HFOT	FiO_2	Flow	Humidification
HFOT	Precise	21 – 100%	1 – 40 LPM	At body temperature and 100%
Low Flow O_2	Variable	Variable	Limited	None

In January 2016, HFOT was used consistently in the Specialty or LTACH units, including patients with tracheostomy tubes. In 2017, Madonna Rehabilitation Hospitals earned recognition as the second Vapotherm Center of Excellence in the United States. A year later, HFOT use was expanded to include the Acute Rehabilitation and Pediatric Hospitals. Currently, use of Vapotherm has been extended to include the long-term ventilator assist unit and the Skilled Nursing Facility level of care. Facility protocols for ventilator weaning and tracheostomy decannulation processes were updated to standardize the safe application of HFOT. In addition, multidisciplinary competencies were developed for staff training that provide for:

- Indications, contraindications, risks, and guidelines.
- Patient safety.
- Application of HFOT.
- Procedures for safety and use.

Indications for Use

HFOT is indicated for patients requiring:

- Humidification of an airway stoma, with or without a tracheostomy tube or larynx tube.
- High oxygen needs.
- A need for high flow therapy.

Patient selection also includes those patients exhibiting increased work of breathing or refractory hypoxemia (generally refers to inadequate arterial oxygenation despite optimal levels of inspired oxygen or onset of barotrauma in mechanically ventilated patients).

Patient Safety and Application

Tracheostomy Tube Application: Connect a patient to HFOT using a 22mm tubing adapter to their tracheostomy mask or T-piece. Do NOT connect the delivery tubing or the tubing adapter directly to a patient's tracheostomy tube (*see Image 1*). ***The tracheostomy tube cuff must be completely deflated when using the Passy Muir® Valve (PMV®)***, including in conjunction with HFOT. If the Passy Muir Valve is not being used, the tracheostomy cuff may remain either inflated or deflated, as needed for the patient.

Nasal Cannula Application: Nasal cannula application may be used during the tracheostomy tube weaning process, when the tracheostomy tube is capped, or with use of the PMV. The nasal cannula application is then utilized for humidifying the upper airway to help jumpstart the natural system and ensure success with secretion mobilization and tracheostomy tube weaning. The flow that is given by the nasal cannula application also helps to flush out the upper airway or dead space of CO_2; decreases work of breathing; and overall, increases patient comfort and satisfaction.

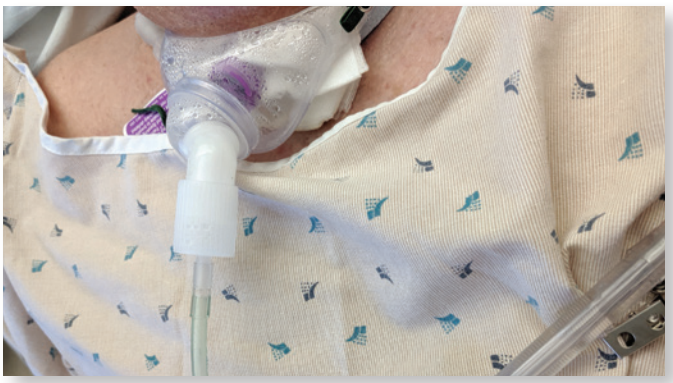

Image 1: Passy Muir Valve on with tracheostomy mask application of HFOT

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Outcomes

Over the last three years of utilizing the Vapotherm, positive outcomes in numerous areas have been observed. Not only have objective changes in care measurements been observed, but patients' anecdotal reports include reports of improvement in comfort, noise, and overall, satisfaction. Staff also reports that HFOT has allowed efficiency of care and participation in therapy, including early mobilization. It also allows the staff to focus on other important patient care needs. Lastly, since the Passy Muir Valve can be used in conjunction with HFOT, communication for the patient is improved and increases their participation in their medical care decisions.

Use of HFOT and the PMV have led to the following changes in quality improvements for patients:

Ventilator Weaning Rates	Tracheostomy Decannulation Rates	VAP Rate
5.3% increase in weaning rates for 2019 as compared to the previous three years	21% increase in decannulation for 2019 as compared with the previous four year average	In 2019, 1.55 occurrences per 1,000 vent days versus 2018, 2.01 per 1,000 vent days

Case Study

Karen, a 74-year-old female, was admitted post-emergent left ventricular assist device (LVAD) placement due to a mixed cardiomyopathy that was related to coronary artery disease and chemotherapy for breast cancer. Her acute care stay was complicated by renal failure, requiring hemodialysis; right ventricular heart failure; and respiratory failure, requiring mechanical ventilation and tracheostomy tube.

Upon arrival, Karen was ventilator dependent 24 hours per day. She required a multidisciplinary team approach to establish an individualized plan of care. This multidisciplinary team consisted of physicians, respiratory therapists, speech-language pathologists, physical and occupational therapists, nutritionist, nursing staff, and others. The initial plan of care included primary goals to address mobility, self-care, ventilator/tracheostomy tube weaning, and dysphagia.

Despite Karen's complex medical history, integrating rehabilitation with medical management would contribute to optimal outcomes. Management included the use of protocols for ventilator weaning and tracheostomy tube weaning. These protocols are typically instituted upon admission as part of the admission order sets and the standard of care. With these protocols, both use of the Passy Muir Valve and HFOT were implemented to improve communication and humidification for the patient. Each healthcare discipline provided a different focus for therapy. The comprehensive plan of care included mobility, communication, dysphagia, self-care, and respiratory management.

Upon admission, Karen was evaluated for mobility, self-care, and swallowing function. Evaluation results indicated that Karen's functional levels upon admission were:

- Maximum Assistance for mobility, transfers, and dressing.
- Minimum Assistance for grooming and eating.
- Severe dysphagia with a determination for nil per os (NPO or nothing by mouth).

At the time of admission, Karen also was ventilator dependent and her ventilator settings were:

- Ventilator Settings without the Passy Muir Valve
  - PC/AC (Pressure Control/Assist Control)
  - Vt (Tidal Volume) = ~500
  - PC (Pressure Control) = 17 cmH_2O
  - PEEP (Positive End-Expiratory Pressure) = 7 cmH_2O
  - RR (Respiratory Rate) = 12 bpm (breaths per minute)
  - FiO_2 of 35%
- Ventilator Settings with the Passy Muir Valve
  - NIV S/T (Non-Invasive Ventilation, Spontaneous Timed)
  - Vt = ~500
  - PC = 28 cmH_2O
  - PEEP = 0 cmH_2O
  - RR = 12 bpm
  - FiO_2 of 30%

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She also was provided with HFOT and the settings for the Vapotherm with the Passy Muir Valve in place were a flow of 20 – 25 LPM, temperature of 37° C, and an FiO_2 of 30%-40%.

Due to Karen's complex medical needs, ongoing assessment and collaboration with the team were necessary throughout her stay. This integrated, multidisciplinary approach ensured that Karen's respiratory needs were met in a safe and effective manner.

With both the input of the multidisciplinary team and the implementation of the appropriate protocols, Karen progressed to the following functional levels:

- Standby assistance for walking and bathing (*see Image 2*).
- Minimum Assistance for dressing; however, her limitations were due to the LVAD and edema.
- Returning to a regular diet without restrictions for food consistency or diet levels. She had a regular diet with thin liquids (*see Image 3*).

Image 2: Karen working with PT to improve her level of mobility by working on stairs

Image 3: Karen enjoying a regular diet and thin liquids when eating

Karen was successfully weaned off the ventilator during her stay. She also progressed to decannulation, having her tracheostomy tube removed (*see Image 4*). The current plan is for her to return home soon. Prior to her discharge home, Karen and her husband will go on a community outing to practice skills and ensure safety.

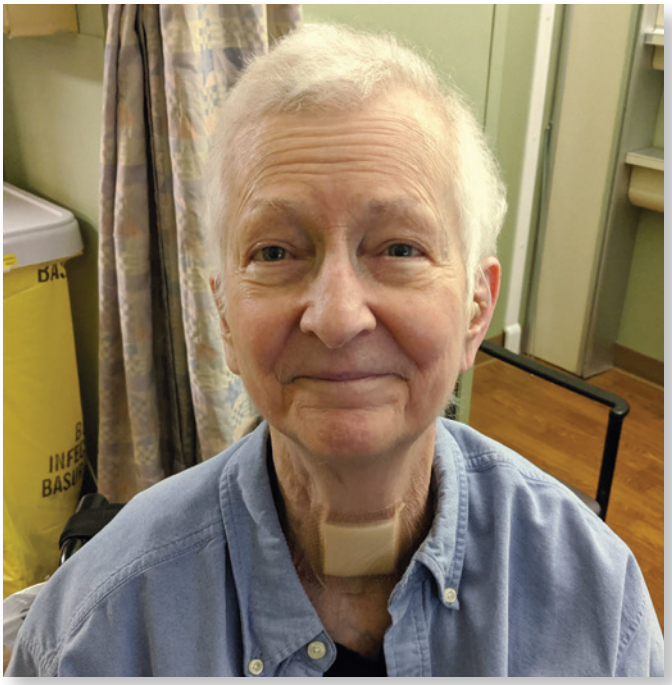

Image 4: Karen following decannulation

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Conclusion: Implementing standard protocols and having a multidisciplinary team providing a plan of care has been shown to improve patient outcomes (Santos et al., 2018). Using both HFOT and a standard decannulation protocol (*see the Decannulation Protocol on page 29*), patients, such as Karen, may progress to higher levels of function and independence (Gotera et al., 2013). A patient with a tracheostomy tube and mechanical ventilation has implications for all clinical professions and each clinician is essential to the plan of care. The use of HFOT has been shown to enhance secretion management and facilitate weaning. It is through the use of standard protocols for HFOT and the PMV in tracheostomy care that facilities have found faster weaning times, which decreases overall lengths of stay and medical costs.

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The Madonna Rehabilitation team

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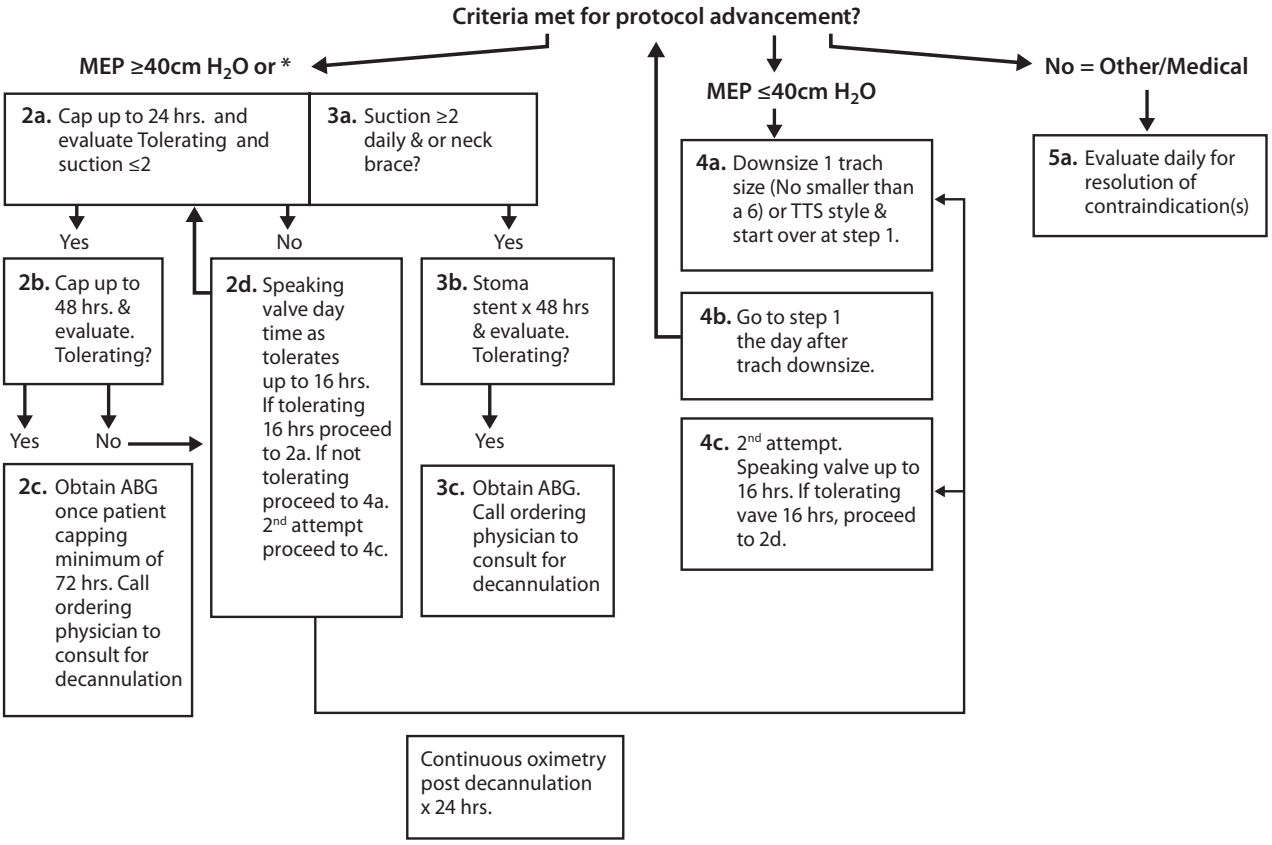
MADONNA
Rehabilitation Hospital

Madonna Rehabilitation Hospital Tracheostomy Decannulation Protocol
For Non-ventilated Patients

Step 1. Criteria for tracheostomy decannulation protocol initiation following successful liberation from mechanical ventilation

- Free of respiratory distress post ventilator liberation for 2 days
- Stable vital signs and absence of fever, sepsis, or untreated infections
- Maximum expiratory pressure ≥ 40cm H_2O (MEP). Notify physician if patient unable to perform MEP.
- Obtain ABG PCO_2 of ≤ 60mm Hg prior to starting protocol unless done in step S6 of the vent wean protocol
- Obtain SpO_2 of ≥ 90% on less than .35 FiO_2 or 4LPM nasal cannula or previous home O_2 regimen
- Absence of know upper airway obstruction or airway disorder such as but not limited to tracheal stenosis and tracheomalcia
- * Spinal cord injury must show ability to clear secretions with manually assisted (Quad) cough *



- Trach decannulation no sooner than 5th day post ventilator liberation.
- If patient is unable to cap on day 3, contact physician for recommendation.
- With protocol assessment a patient may advance to the step they are currently weaning however decannulation no sooner than 5 days post ventilation dependence without physician order.
- Pysician must be called upon completion of trach wean protocol and readiness to decannulate for final decannulation order.
- This protocol is a physician order for trach capping and speaking valve use as detailed in this protocol.
- Speaking valves are never for use during sleep.

Infants and Children with Tracheostomy and Ventilator Dependence in the Intensive Care Units: Candidacy and Early Intervention with a Bias-Closed, No-Leak Speaking Valve

Laura Brooks, MEd, CCC-SLP, BCS-S

Extensive research on the Passy Muir® Tracheostomy & Ventilator Swallowing and Speaking Valve (PMV®) exists within the adult population to support the benefits of voicing, secretion management, physiologic PEEP, swallowing, olfaction, quality of life, and weaning. However, working with infants and children, who have tracheostomies with or without ventilator support, can be more challenging than with adults due to multiple factors. Developmental factors, in combination with medical concerns, impact treatment considerations, but the research literature in the pediatric population is inadequate to provide sufficient evidence-based practices (Suiter et al., 2003). Review of recent literature suggests that approximately half of all pediatric patients who receive a tracheostomy are younger than one year of age (Barbato et al., 2012; Lewis et al., 2003). Early tracheostomy may lead to an opportunity for early application of the PMV that may otherwise be missed if the medical team does not have a clear understanding of practice guidelines for PMV application.

Because of the paucity of research in pediatrics, it is challenging to have consensus among physicians and clinicians regarding candidacy for Passy Muir® Valve application with medically complex infants and children. This is particularly difficult for infants in the Neonatal Intensive Care Unit (NICU), patients who are ventilator dependent, and individuals with airway compromise (i.e. stenosis or vocal fold paralysis). As a result, patients who may be a candidate for Valve placement may not receive this intervention due to physician concern for use in what is viewed as a higher risk population.

Therefore, it is critical that the speech-language pathologist has a thorough understanding of the ventilator and the patient's specific settings, how the PMV changes the mechanics of inspiration and expiration when on the ventilator, and medical co-morbidities that may compromise successful PMV application. The clinicians and facility should have a practice guideline in order to ensure consistent application of the PMV and to provide an understanding of any potential contraindications.

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Understanding the Ventilator

The PMV was invented for use in-line with ventilator circuitry (for patients who are ventilator dependent) by a patient who was ventilator dependent. It is a bias-closed, one-way Valve that allows inspiratory support from the ventilator and allows 100% of exhalation to occur out through the patient's nose and mouth. For best practice, the PMV is typically placed in the ventilator circuit and not directly on the tracheostomy hub. Placement of the PMV on the hub of the tracheostomy tube may create torque. If torque or movement of the tracheostomy tube occurs, there is a higher risk for potential tissue erosion, laceration of the skin, or an exacerbation of granulation tissue growth (Keens et al., 2017). Because of the variety of hospital and home ventilators and circuits, clinicians and caregivers must understand the differences between them and the level of support that the patient is receiving from the ventilator.

Some ventilators are designed for use with patients in intensive care units. These ventilators are precise and most frequently used for higher risk patients, who require more ventilator support. Home ventilators, such as the LTV and Trilogy, are more portable, less expensive, and may be used for patients transitioning from the ICU to the acute care floor and then to home. Pediatric candidates for home ventilators are children who have relatively stable ventilator settings, with lower FiO_2 (<40%) and peak inspiratory pressure (PIP) (<40 cmH_2O) (Keens et al., 2017).

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When working with patients on mechanical ventilation, an understanding of the ventilator settings and patient parameters is essential for all healthcare professionals. There are two primary types of ventilation: pressure controlled and volume controlled. A physician orders the type of ventilation, depending on the patient's needs. The following terms are some of the common terms related to the care of a patient on mechanical ventilation with which the healthcare professional should be familiar:

Breath Types:

Volume breath: Ventilator delivers a pre-set volume, regardless of the pressure required to do so. Volume is constant, whereas pressure is variable (pressure varies depending on lung compliance/resistance).

Pressure breath: Ventilator delivers a pre-set pressure over a pre-set inspiratory time. Pressure is constant, whereas volume is variable (volume varies depending on lung compliance/resistance).

Common Modes of Ventilation:

Pressure Control Ventilation (PC or PC/PS): Ventilator delivers a predetermined number of breaths per minute, with a pre-set pressure over a pre-set inspiratory time. Pressure support may be provided during spontaneous breathing on some ventilators.

Assist Control (A/C): Ventilator delivers a predetermined number of breaths per minute, using either a specified volume or pressure. All triggered breaths are fully supported.

Synchronized Intermittent Mandatory Ventilation with Pressure Support (SIMV/PS): Ventilator delivers a predetermined number of breaths per minute using either a specified volume or pressure. Pressure support is provided during the spontaneous breath.

Pressure Regulated Volume Control (PRVC): Ventilator adjusts the pressure delivered during each breath to ensure target volumes are delivered.

Pressure Support with Continuous Positive Airway Pressure (PS w/ CPAP): Continuous positive airway is maintained during exhalation, while each spontaneous breath is supported with a set pressure.

Ventilator Settings (what the physician orders):

Breath types:

Pressure breaths: Physician orders set pressure.

Volume breaths: Physician orders set volume.

Positive End-Expiratory Pressure (PEEP): Amount of pressure that remains in the lungs at the end of exhalation.

CPAP: Continuous positive airway pressure.

Pressure Support (PS): Positive pressure provided during a spontaneous breath.

Respiratory Rate (RR): Number of breaths per minute delivered by the ventilator.

Fraction of Inspired Oxygen (FiO_2): Percentage of oxygen the ventilator delivers. For reference, room air has FiO_2 of 21%.

Tidal Volume (Vt): Volume of gas inhaled with each breath, recorded in cc/ml. Physicians prescribe tidal volume using ideal body weight and lung pathology.

Other:

Peak Inspiratory Pressure (PIP): Highest level of pressure applied to the lungs during inhalation.

End-Tidal Carbon Dioxide ($EtCO_2$): Capnograph measures exhaled CO_2. This value can either be found on the ventilator or on a separate machine. $EtCO_2$ readings may indicate the quality of ventilation or cardiac output and is the gold standard to confirm endotracheal tube placement.

Partial Pressure Carbon Dioxide ($PaCO_2$): Measured from an arterial blood sample. Normal values range from 35-45 mmHg.

Inspiratory Time/I-Time: Duration of inspiration in seconds.

Indications for the Tracheostomy

When working with this patient population, it is important to understand the indications for a tracheostomy. The disease process and reason for tracheostomy may impact the timing of intervention as it relates to PMV use. With infants and children, several causes may lead to a tracheostomy. Three main categories of tracheostomy indications include airway obstruction, lung disease, and neuromuscular/neurological involvement. These categories include, but are not limited to, chronic obstruction within the airway, such as choanal atresia, subglottic stenosis, tracheomalacia, laryngomalacia, and bronchomalacia;

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vocal cord paralysis, leading to chronic aspiration or poor pulmonary toileting with an inability to clear secretions; severe CNS (Central Nervous System) impairment, such as seen with Arnold-Chiari malformation, Werdnig Hoffmann disease, and Congenital Hypoventilation Syndrome; craniofacial anomalies, such as seen with Pierre Robin sequence and Treacher Collins, Beckwith-Wiedemann, and CHARGE syndromes; and chronic lung disease, including bronchopulmonary dysplasia (Shaker & Mutnik, 2012). Timing of interventions and establishing access to the upper airway for communication, speech-language development, cough, and other pulmonary functions is crucial. Early intervention and use of a PMV provides benefits which may assist in the recovery process.

If the patient has neurologic indications for a tracheostomy, but the lungs are healthy and the muscles are weak, these patients generally do not require frequent changes in ventilator settings (Keens et al., 2017). For patients with upper airway anomalies requiring a tracheostomy, the ability of the patient to adequately exhale around the tracheostomy tube is of concern and would need to be considered during the evaluation. This diagnosis may even require a Direct Laryngoscopy and Bronchoscopy (DLB) to be performed by the otolaryngologist. This assessment would address the severity of the obstruction. Because of the wide variety of causes for a tracheostomy, the history provides crucial information which may impact the assessment process.

Understanding the Impact of a Cuff and Its Proper Management

Generally, uncuffed tracheostomy tubes are the preferred tracheostomy tube type for children. However, patients with severe restrictive lung disease or neuromuscular disease require a high pressure be delivered, and it is done more effectively with the cuff inflated (Hess & Altobelli, 2014). Previously, only uncuffed tracheostomy tubes were available for pediatrics, but in the past decade, cuffed tracheostomy tubes have become more popular (Watters, 2017). The choice of cuffed versus uncuffed tracheostomy tubes is usually institution or patient dependent. The uncuffed tracheostomy tube has benefits not observed in cuffed tracheostomy tubes, such as reducing the incidence of acquired tracheal wall injury (Hess & Altobelli, 2014) and improving phonation (DeMauro et al., 2014; Cowell, Schlossler, & Joy, 2000).

The patient with an uncuffed tracheostomy tube also may have less difficulty with the application of the PMV as there is less change in the exhalation physiology. Typically, a patient inhales and exhales through the tracheostomy tube, which is either cuffed or cuffless. Cuffed trach tubes must be completely deflated prior to PMV application, and the deflated cuff material may still cause some resistance when exhaling (Beard & Monaco, 1993). A tight to the shaft (TTS) tracheostomy tube or uncuffed tracheostomy tube may allow for more space in the tracheal lumen for exhalation out through the mouth and nose. When the PMV is placed, a child still inhales through the Valve and tracheostomy tube, but the Valve closes at the end of inspiration and redirects airflow out through the upper airway, mouth, and nose. For children, the most common reasons for PMV success involve both physiologic and behavioral factors (Lieu et al., 1999). As such, uncuffed tracheostomy tubes can help prepare the patient physiologically and behaviorally for the change in exhalation. Additionally, an uncuffed tracheostomy tube has the potential to allow the patient to sense the secretions in their pharynx, resulting in a swallow or cough in response. One study with critically ill patients with a tracheostomy, who were randomized to groups, found that deflating the tracheostomy tube cuff shortened weaning time, reduced respiratory infections, and improved swallowing (Hernandez et al., 2013).

Another Consideration: Ventilator Circuits

When working with a patient who is ventilator dependent, the speech-language pathologist (SLP) and the respiratory therapist (RT) must be familiar with the different ventilator circuits that may be used. The type of circuitry will dictate the type of adapters that may be needed for successful placement of the PMV in-line with the ventilator circuit. The types of adapters are usually either a 15/22 mm step-down adapter or a 22mm silicone adapter (*see Image 1*).

It is important to understand the different circuits and know whether the patient is on a single limb circuit or double limb circuit. In addition, the team should be aware if the circuit is a passive circuit or an active circuit. An example of a ventilator that has both an active and passive circuit that is used often in pediatrics is the Trilogy. Both circuits are single limb circuits. The passive circuit has the whisper swivel valve, and the active circuit has a mushroom valve for exhalation. With the passive circuit, the PMV is used with patients who require pressure ventilation. With an active circuit, the PMV is used with patients who are volume ventilated.

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Image 1

PMV-AD1522™ Step-down Adapter (on left):
Color coded for use with the PMV® 007 (Aqua Color™), the adapter provides a secure connection between the Passy Muir Valve and ventilator tubing, closed suction systems, or other adapters. 15mm OD – 22mm ID.

PMV-AD22™ Flexible Silicone Adapter (on right):
Color coded for use with the PMV® 2001 (Purple Color™), the adapter provides a secure connection between the Passy Muir Valve and tubing, closed suction systems, or other adapters. Stretches to fit 22mm.

The SLP and the RT work together as a team and rely heavily on the expertise and support of the other team members when determining patient candidacy, problem solving ventilator application, and evaluating and treating the patient for Valve use. For successful application and early intervention in critical care, all team members should have extensive understanding of PMV use; otherwise, there may be roadblocks to early application of the Valve on a patient who is ventilator dependent. While the SLP should be educated on ventilator settings, modes, and circuits to help advocate for application of the PMV, the SLP relies on the expertise of the RT for ventilator adjustments and patient safety. The RT relies on the SLP to provide assessment of voice, swallowing, speech and language skills, and cognition.

Application of the PMV:
How to Maximize Safety and Success

Understanding the value of the PMV application for patients and the benefits that may be achieved assist with improved patient use and care. However, many patients are underserved due to a lack of clinician and physician consensus for understanding the range of benefits and for determining candidacy. Members of the medical team may ask such questions as: is this patient too young? Too small? Too sick? On too much PEEP? Can the patient tolerate the PMV with any degree of airway obstruction or narrowing?

The benefits of using a bias-closed, one-way valve have been reported in the literature and include access for the infant to be able to communicate via cries and other sounds; have improved taste and smell; generate subglottic pressure for cough, cry, and swallowing; reduce the potential for further vocal cord dysfunction; restore laryngeal/pharyngeal sensation; and improve secretion management (O'Connor, et al., 2019; Hull, et al., 2005; Torres & Sirbegovic, 2004). Abraham (2009) investigated the use of a PMV in children and reported that children wearing a Passy Muir Valve during waking hours normalized secretion management within two weeks due to improved sensation of secretions. Benefits also were reported for reduced time to decannulation and restored physiologic PEEP, which led to diminished WOB (work of breathing) (Hull et al., 2005; Torres & Sirbegovic, 2004; Sutt et al., 2016).

Review of the current literature supports safety of PMV application with certain patients, depending on the medical comorbidities. Passy Muir Valves have been used with both pediatric and adult populations, with the PMV being used with infants as young as one day old and within the NICU (Torres & Sirbegovic, 2004). Some specialists may have concerns that an infant's airway is too small and will not have enough room around the tracheostomy tube (Torres & Sirbegovic, 2004). However, the concerns related to upper airway patency may be assessed in two different ways: visual observation by the otolaryngologist via DLB and testing with manometry. If it is determined initially that the patient's upper airway is not patent via endoscopy or manometry, then the infant should be followed and retested, as appropriate, during their admission. Retesting is warranted because an infant or young child may have significant improvement in airway patency secondary to changes in age, weight, or growth which may affect the size of the trachea.

Once it is established that the patient is a good candidate and has a patent upper airway, additional criteria are considered. For Valve placement, the following criteria may be considered for patients who are ventilator dependent:

a. The patient must tolerate cuff deflation. Set the patient up for success by slowly deflating the cuff. Some patients may even require deflation to take place over several minutes to adjust to the change in airflow (Hess & Altobelli, 2014).

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b. PMV, in the pediatric population, should be trialed following the patient's first trach change. The first trach change is often done by the surgeon as the immature stoma poses some risk for damage (Hess & Altobelli, 2014).

c. The patient must be hemodynamically stable.

d. Contraindications for PMV application:

   i. Significant upper airway obstruction (e.g. grade 4 subglottic stenosis).

   ii. Thick secretions.

   iii. Foam-filled cuff, as these cuffs cannot be safely deflated (Hofmann, Bolton, & Ferry, 2008).

   iv. With the Trilogy ventilators: For the passive circuit, use the PMV with patients who require pressure ventilation. With an active circuit, use the PMV with patients who are volume ventilated.

e. FiO2 < 50%

f. PEEP $\leq$ 10 cmH_2O

g. PIP/PAP= $\leq$ 40 cmH_2O

* *some variation exists between facilities (e.g. some use PEEP of 12 or less).*

It is recommended that the medical team continue to apply heated humidification. However, a heat-moisture exchanger (HME) should not be used with the PMV, as no exhaled gas passes to the HME through the tracheostomy tube when the Valve is in place (Hess & Altobelli, 2014).

When using the Passy Muir Valve during mechanical ventilation, respiratory therapists may make some adjustments, under physician direction, to improve patient comfort and safety. Some common and simple adjustments may include:

Reduction or elimination of PEEP:
The establishment of a closed respiratory system and exhalation through the oronasopharynx restores physiologic PEEP. This enables the clinician to reduce or eliminate set mechanical PEEP (Sutt et al., 2016). This adjustment may also eliminate any unnecessary continuous airflow within the circuit. Continuous flow in the circuit may make it difficult for the patient to close the vocal cords and may stimulate continuous coughing and auto-triggering of the ventilator.

Volume compensation:
For patients with inspiratory volume loss, after cuff deflation, additional Tidal Volume (Vt) may be provided until baseline Peak Inspiratory Pressure (PIP) is reached. When considering use of a PMV with mechanical ventilation, factors such as inspiratory support may be managed by ensuring the patient achieves baseline Peak Inspiratory Pressures.

Alarm adjustments:
All alarms on the ventilator must be re-evaluated for appropriate adjustments before, during, and after use of the Valve. Proper alarm management is essential for patient safety and best standard of care.

Options for alarm management are dependent upon facility policy. Patient safety is the priority and proper management of the ventilator is key. With clear understanding of the ventilator and the changes that the PMV applies to the respiratory system, the members of the care team may advocate for adjustments for best practice and improved likelihood of patient satisfaction and comfort (ordered by the physician). It is recommended that a procedure be in place to identify when settings were changed. Proper documentation allows for the ventilator to be returned to the baseline settings when the PMV is removed.

Manometry: Measuring Transtracheal Pressure and Ensuring Airway Patency

To address the issue of the airway and atypical airflow, the step of assessing airway patency with manometry may provide information to the medical team regarding the patient's ability to exhale adequately around the trachea. If there is obstruction and the patient cannot adequately exhale, pressure can incrementally increase with each breath, known as breath stacking or air trapping (Hess, 2005; Hofmann et al., 2008). Additionally, a higher end-expiratory pressure reading with manometry may indicate patient discomfort, even if the patient is not breath stacking.

For medically complex infants in ICUs, initiating Transtracheal Pressure (TTP) testing as part of every PMV assessment is a helpful tool for objective feedback to physicians and the team regarding safety and readiness for Valve application. Transtracheal pressure testing equipment includes a manometer to be applied within the ventilator circuit with O_2 tubing and an adapter. Adapters, such as the 15/22mm step-down adapter or a 22mm silicone adapter (*see Image 1*), may be added into the circuit as well

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as aiding proper fit of the Valve. The assessment team, typically respiratory therapy and speech-language pathology, determines how to place the Valve into the circuit, with and without the manometer.

Image 2

Transtracheal Pressure (TTP) measurement equipment with Tracheostomy P.A.M.™ (Pediatric Airway Model).

A TTP value is the number at the end of the exhalation or end-expiratory pressure with resting breaths only. This reading provides the patient's physiologic PEEP (positive end-expiratory pressure). When placing the PMV, a closed system is reestablished which restores a more normal physiologic PEEP, as compared to the PEEP provided by the ventilator. An adequate TTP reading provides feedback to the team that the airway is patent, and the patient may adequately exhale around the tracheostomy tube. The pediatric population presents a special challenge during evaluation because any movement or vocalization will increase the pressure and compromise the ability to read resting breaths. If an infant is crying, moving, vocalizing, or pushing, the pressures will be increased, and it will not be an accurate reading. Challenges with pediatrics occur not only because of the smaller anatomy but due to the difficulties with following specific directions, such as "just breathe" or "don't move."

One option to address these issues is to obtain TTP readings while the patient is sleeping in order to test true resting breaths, as the measurement can be taken in as little as 20 seconds. However, the team should consider that despite current literature supporting application of the PMV during sleep (Barraza et al., 2014), use of the Valve during sleep is an off-label use. Alternatives to placing the Valve for TTP measurement during sleep is to catch the child in either a drowsy state or to distract with toys or videos.

Another consideration is the current discrepancy as to what value is deemed acceptable, meaning what TTP reading or number demonstrates that the airway is patent, and the patient may comfortably and adequately exhale around the tracheostomy tube. An early study suggested that a tracheal pressure greater than 5 cmH_2O during passive exhalation may indicate excessive expiratory resistance (Hess, 2005). However, most studies have reported that pressures in the range of 2-6 cmH_2O indicate a patent airway and that assessment for use of the Valve may occur (Barraza et al., 2014; Buswell et al., 2016). Additionally, recent research has indicated that children with end-expiratory pressure up to 10 cmH_2O may tolerate the Valve (Utrarachkij, et al., 2005). In an earlier study, Trotter (1995) found accurate predictions for success with the PMV occurred when patients' end-expiratory pressures were 15 cmH_20 or lower. Trotter also indicated that SpO_2 was not a good predictor for Valve use. The literature provides a range of airway patency measurements at which predicting success for Valve use has occurred. The use of TTP is one method for providing an objective measurement that may assist with evaluating patients and may identify potential airway difficulties or even successes. Due to the range of measurements, further research is warranted.

Obtaining an accurate TTP reading requires a good understanding of respiratory and ventilator basics, such as PIP and PEEP, and the differences between ventilators and circuits. Therefore, it may be helpful initially to test airway patency via manometry to obtain baseline measurements without the PMV. Generally, the manometer, without the PMV in place, will read PIP (inspiration) to PEEP (peak end-expiratory pressure) values, which are similar to what is set with the ventilator. For example, if the patient's ventilator is set to a PEEP of 8 cmH_2O and a PIP of 20 cmH_2O, the manometer should fluctuate between 8-20 cmH_2O with each breath. This consistency may provide a means of calibrating the TTP and identifying accurate readings. Although, at times, the PIP value on the manometer may be slightly lower than the ventilator PIP, such as when there is an exhalation valve, as seen with the Trilogy.

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Once the SLP and RT obtain a patient's manometry baseline, the PMV is placed in-line with the manometer and adapters. With resting breaths only, the TTP reading is the value at the end of exhalation. While this process may seem simple, in actuality, it is challenging to get accurate readings without proper training. The numbers may be misread, especially if a clinician is not familiar with the ventilator, respiratory function, or manometry readings. Importantly, the clinician should not initially read the high number as the inhalation or PIP and the low number as the exhalation or PEEP. In fact, with initial placement, a high number may be the exhalation, but once the patient settles and resting breaths are measured, the high number may be the PIP. It is helpful to watch the baby or child and the manometer for indicators. The RT also contributes information from the ventilator by monitoring inhalation via the ventilator and providing an indication when the patient is at the end of exhalation. Marking the end of exhalation provides a more accurate reading for expiratory pressure. Watching the infant's chest rise and fall provides relevant information as well. TTP readings may be impacted by position and state, so pressures may need to be retested if the child is moving, agitated, crying, or engaging in other activities that may interfere with readings. Because of the factors that may impact TTP measurements, the SLP and RT may need multiple sessions to get a proper measurement.

If the pressure is too high, breath stacking occurs, or discomfort is visible during exhalation through the nose and mouth, the following should be considered:

1. Repeat the DLB/endoscopy to examine the airway.
2. Downsize the tracheostomy tube (Mehta & Chamyal, 1999).
3. Change from a cuffed tracheostomy tube to an uncuffed one (Hess, 2005).

It should be noted that even if the airway is patent, other factors can interfere with use of the PMV. Therefore, the SLP and RT must offer the opportunity to use the Valve safely and consistently (Hull, 2005).

A Facility's Guideline to Passy Muir Valve Application and Best Practice

With limited research on PMV application in the pediatric, medically complex, ventilator-dependent population, it is recommended that facilities develop best practice guidelines for PMV application. Often these guidelines have input from and are approved by pulmonology, otolaryngology, respiratory therapy, and speech-language pathology, among other specialties. To provide best practice and state-of-the-art care for the medically complex, pediatric patient with tracheostomy or ventilator dependence, it is essential that the clinical professionals be familiar with all aspects of respiratory function, including appropriate interventions and assessments, to enhance access to and use of the PMV.

This sample guideline provides suggested steps for patient selection; proper ventilator and alarm considerations; and assessment and application processes for use of the PMV in the pediatric patient population:

I. PROCEDURE:

A. Criteria for candidacy:
   a. Placement after first trach change.
   b. Tolerance of cuff deflation.
   c. Being hemodynamically stable.
   d. Physician to review the most recent airway examination and determine if follow up is needed, before Valve placement.
   e. Physician to consider indication for tracheostomy, size of tracheostomy tube, and upper airway obstruction to determine if a patient is a candidate for Valve placement.
   f. Patient's age and weight.
   g. Contraindications:
      i. Significant upper airway obstruction per ENT or pulmonology.
      ii. Copious, thick secretions.
      iii. Foam-filled cuff.
      iv. Airway stenting.

B. Ventilator parameter recommendations for candidacy:
   a. $FiO_2 < 50\%$
   b. PEEP $\leq$ 10 cmH_2O
   c. PIP/PAP < 40 cmH_2O

C. Application of PMV for patients who are on a ventilator.
   a. Physician to order:
      i. Passy Muir Valve trial (Respiratory order) through SLP consult.
      ii. SLP conducts bedside evaluation, in conjunction with respiratory therapy.
   b. Supplies for in-line placement *(see Image 1)*.

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c. Pressure testing supplies *(see Image 2)*.
d. Position patient upright.
e. Observe baseline vitals.
f. Oral care and suctioning, as needed.
g. RT to:
    i. Deep suction tracheostomy, if needed.
    ii. Observe PIP and exhaled Vt.
    iii. Deflate cuff slowly.
    iv. Suction trach and mouth again, as needed.
    v. Look for loss of exhaled Vt.
    vi. Observe changes in vitals, color, work of breathing, and signs of stress.
h. Proceed, if tolerating the above steps.
i. Apply PMV and transtracheal pressure manometry in-line with the ventilator circuitry (not directly to the tracheostomy hub so as to avoid torque) with adapters and pressure testing supplies. Monitor transtracheal reading/pressure testing, which measures end-expiratory pressure.

D. Application of PMV for patients with tracheostomy tube only (without a ventilator)
a. Physician order.
b. SLP conducts bedside evaluation for use of PMV, in conjunction with RT, for initial placement.
c. Pressure testing supplies *(see Image 2)*
d. Position patient upright.
e. Observe baseline vitals.
f. Oral care and suctioning, as needed.
g. RT to deep suction trach, if needed.
h. Slowly deflate cuff.
i. Suction trach and mouth again, as needed.
j. Observe changes in vitals, color, work of breathing, and signs of stress.
k. Support tracheostomy tube neck flange with one hand and gently apply PMV and transtracheal pressure manometry to the tracheostomy hub, using a gentle quarter turn twist to the right to seat the Valve on the tracheostomy hub. To remove, support the tracheostomy tube neck flange and turn to the right, while using a gentle pulling off motion.
l. Monitor transtracheal reading/pressure testing, which measures end-expiratory pressure.
m. Monitor stability.
n. Pressure reading values:

Likely Pass: Resting TTP < 10 cmH_2O	**10-20 cmH_2O, Borderline**	**Possible Fail: Resting TTP > 20 cmH_20**
1. Action: Proceed with PMV trial. **a.** Children with mean TTP < 5 cmH_20 are more likely to proceed to full tolerance status. **b.** Children with mean TTP 5-10 cmH_2O- likely to cope with longer 1:1 supervised trials.	**1. Action:** Proceed with short trials with SLP, as tolerated. **2.** Closely monitor for work of breathing or stress signs.	**1. Action:** Review possible confounding effects. **a.** If deemed inaccurate, action is to retrial. **b.** Contact ENT. Next steps may include assessment of upper airway or downsizing tracheostomy tube.

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E. Signs that the patient has not tolerated the Valve
   a. Significant change in vitals with cuff deflation or Valve placement.
   b. Stress signs, such as changes in color or increased work of breathing.
   c. High-pressure testing with TTP.
   d. If a "whoosh" sound occurs when the Valve is removed following resting breaths, there is a concern for breath stacking.

F. Additional information:
   a. The patient may cough because of an increased sensation of secretions. This type of cough is not a sign of poor PMV tolerance.
   b. Oxygen may be delivered via T-piece, trach collar, PMV oxygen adapter, or ventilator.
   c. Humidity may be provided via a tracheostomy collar or T-piece. Humidification does not affect the function of Valve.
   d. Alarms may need to be adjusted or managed by RT with physician orders.

G. Following the PMV trial
   a. Either the SLP or the RT will document the patient's ability to wear the Valve.
   b. The SLP, RT, and ordering physician will determine the plan for ongoing Valve trials, and the physician will write any appropriate orders.
   c. Ongoing pressure testing will likely not be completed, unless concerns are noted.

PMV® 007 (Aqua Color™)

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

Jenny Opalinski, MA, CCC-SLP | Kaitlin M. Hanley, MS, CCC-SLP

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).

The combination of EMT and PMV may be beneficial for improving the deficit areas often seen in the critically ill.

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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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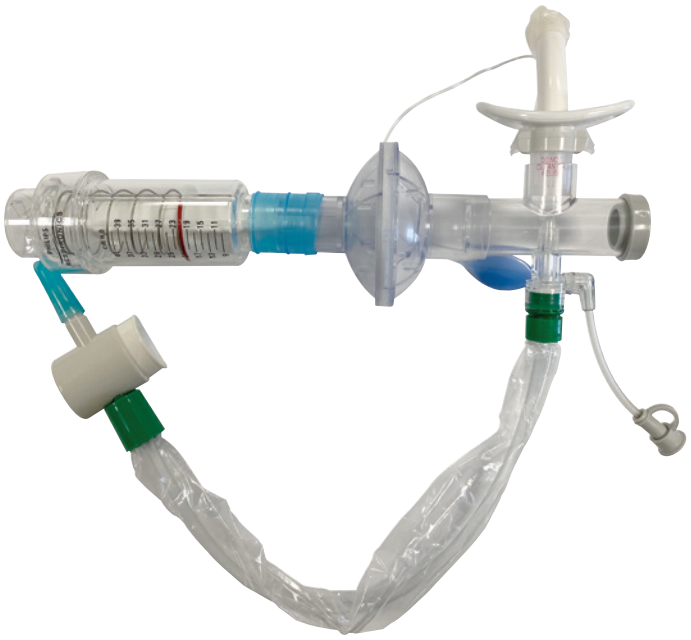

Setup for IMT and EMT with pressure threshold devices and bacterial filters.

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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Clinical Hot Topic Box | Tiffany Oakes, MS, CCC-SLP

Oral Health Screening

Sample oral care kit supplies include:

- Toothbrush (suction toothbrush)
- Toothpaste (consider non-foaming)
- Oral swabs
- Distilled water
- Oral antiseptic
- Clean cloth, gauze, or wipe
- Basin
- Lip balm (mouth moisturizer)
- Denture adhesive, if needed

Sample components of an oral health screen include assessing:

- Quality and quantity of oral secretions
- Condition of oral mucosa
- Appearance of the lips
- Condition of dentition:
  - Presence of dentures (and fit)
  - Broken, missing, or decayed teeth
- Appearance and mobility of the tongue
- Signs of lesions, ulcers, or redness
- Signs of infection or injury
- Presence of any residue
- Level of dependence for performing care

Wear Time Tips & Troubleshooting

| Kristin A. King, PhD, CCC-SLP | Gail M.Sudderth, RRT

PROBLEM	TIPS & TROUBLESHOOTING
Excessive coughing:	1. Use slow cuff deflation. 2. Cue patient to clear secretions orally or suction again. 3. Remove Valve and check for complete cuff deflation. 4. Check tracheostomy tube alignment and body positioning. 5. Consider tracheostomy downsize or different tracheostomy tube type. 6. Introduce Valve slowly – seconds of wear at a time. 7. If coughing persists, consider ENT consult.
Honking noise with Valve use:	1. Clean the Valve according to manufacturer's instructions. 2. If no improvement: a. Work with the patient on how to breathe with the Valve, b. Work on controlled exhalations, c. Address respiratory support for breathing and speech, d. Present relaxation techniques, e. Or try other methods to normalize respirations. 3. Intermittent honking may require an ENT evaluation to assess vocal fold function or for airway anomalies. 4. Consider tracheostomy tube size and potential for downsizing. 5. If honking occurs after extended use of the Valve and cleaning does not work, consider replacing the valve.
Limited or strained voicing, with decreased airflow through the upper airway:	1. Remove the Valve and assess factors affecting airway patency. 2. Ensure cuff is completely deflated. 3. Check tracheostomy tube alignment and body positioning. 4. Suction again, if needed. 5. Consider tracheostomy tube downsize or different type. 6. Consider ENT consult.
Weak cough or voicing, with good airflow through the upper airway:	1. Check the patient's position for good breath support. 2. Assure the position of the tracheostomy tube is in alignment. 3. Consider respiratory muscle strength training (RMST) to improve breath support. 4. Consult SLP for assessment, if not working with the patient. 5. Consider ENT consult for assessment.
Air leak around stoma during Valve use:	1. Consider silicone stoma pad. 2. Consider a hydrophilic dressing.
Good airway patency, but difficulty saturating:	1. Consult RCP. 2. Consider low flow supplemental oxygen via humidified nasal cannula. 3. Work with the patient on breathing techniques to increase deep breathing and coordination of respiration and speech with appropriate pausing.
Back pressure noted with Valve removal:	1. Stop Valve use and reassess airway patency. 2. Consider evaluating airway patency by measuring transtracheal pressure (TTP) with manometry. 3. Assess patient for anxiety, stress, or tension as potential causes. 4. Consider tracheostomy downsize or different type. a. Consider a TTS (tight to shaft cuff) tracheostomy tube. 5. If no improvement, consult ENT to evaluate cause.

Laura Brooks, MEd, CCC-SLP, BCS-S

Laura attended the University of Florida, finishing in 1997, and the University of Virginia, graduating in 1999. She worked at NYU Medical Center, became the supervisor of the pediatric SLP department, and then joined Children's Healthcare of Atlanta in 2009. She works with patients in the intensive care and acute care units; is board certified in swallowing and swallowing disorders; and participates in research related to tracheostomies, speaking valves, and evidence-based care.

Biswajit Chakrabarti, MD, FRCP

Biswajit Chakrabarti completed his undergraduate training at the Imperial College of Science, Technology and Medicine in London, UK prior to undertaking Specialty training in Respiratory Medicine including a research fellowship in the field of COPD and Ventilation. He was appointed as a Consultant in Respiratory Medicine in 2008 at University Hospital Aintree, Liverpool where he is one of the principal physicians at the Ventilation Inpatient Centre which acts as the regional Ventilation and Weaning centre. His specialist interests include Sleep Medicine, Ventilation, and Pleural disease.

Rinki Varindani Desai, MS, CCC-SLP, CBIS, CDP

Rinki Varindani Desai is an ASHA-certified Speech-Language Pathologist, BIAA-certified Brain Injury specialist, and NCCDP-certified Dementia Practitioner; specializing in the assessment and treatment of cognitive, linguistic and swallowing disorders in adults. She founded the *Medical SLP Forum*, co-created the *Dysphagia Therapy* mobile app, and co-founded *Dysphagia Grand Rounds* and the *Swallowing Training and Education Portal.* Rinki currently serves as Associate Editor for ASHA's SIG 13 Perspectives, Co-Chair of Dysphagia Research Society's *Website, Public Relations and Communications Committee,* and on the National Foundation of Swallowing Disorders' *Global Task Force for Dysphagia.* Originally from Mumbai, India, Rinki currently practices in Dallas, Texas.

Melissa Gulizia, BS, RRT

Melissa Gulizia is currently the Pulmonary Program Manager at Madonna Rehabilitation Hospitals. She has worked at Madonna for 12 years in numerous roles across the continuum. Melissa is a graduate from Southeast Community College in 2006 with an AAS in Respiratory Therapy followed by a BS in Health Care Management in 2011 from Bellevue University. In addition to holding leadership roles, she has provided direct patient care, interdisciplinary education, trainings, and consultations to facilities in the region.

Kaitlin M. Hanley, MS, CCC-SLP

Kaitlin Hanley is a senior speech-language pathologist in acute care at NYU Langone Health Center. Clinical areas of interest and expertise include working with patients who have neurological disorders, patients following organ transplants, patients requiring critical care, as well as performing instrumental swallow evaluations on complex patients.

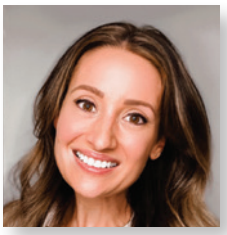
continued next page

Michael Harrell, BSRT, RRT

Michael Harrell has experience in respiratory care clinical practice, education, and management. Prior to joining the Passy-Muir clinical team in 2005, he was a Director of Respiratory Care in Florida. Michael also presided as President of the Florida Society of Respiratory Care where he brought together his clinical knowledge and strong advocacy for patient care to improve respiratory care in the state of Florida. In his role as Director of Clinical Education-Respiratory with Passy-Muir, Inc., he has presented both domestically and internationally.

Kristin A. King, PhD, CCC-SLP

Dr. Kristin King is Vice President of Clinical Education and Research at Passy-Muir. She has over 25 years of experience in medical speech-language pathology in the clinical, academic, and industry settings. Her relevant clinical experience is with complex medical patient populations both in pediatrics and adults, addressing dysphagia, traumatic brain injury (TBI), and tracheostomy and ventilator-dependent patient populations. She has conducted research investigating the impact of neuropathological disorders on communication and cognition, with a special emphasis on sports concussions. She maintains her clinical skills through consultative services and research collaborations with healthcare professionals. As a recognized subject matter expert in TBI, she also has participated in the development of content for various resources, such as the ASHA Practice Portal, and has acted as an expert witness. She also has published in peer-reviewed and clinical journals and regularly presents domestically and internationally on topics related to patients following TBI or patients with tracheostomies and speaking valves. She develops and oversees educational programming in multi-media formats, including print, video, and audio.



Jenny Opalinski, MA, CCC-SLP

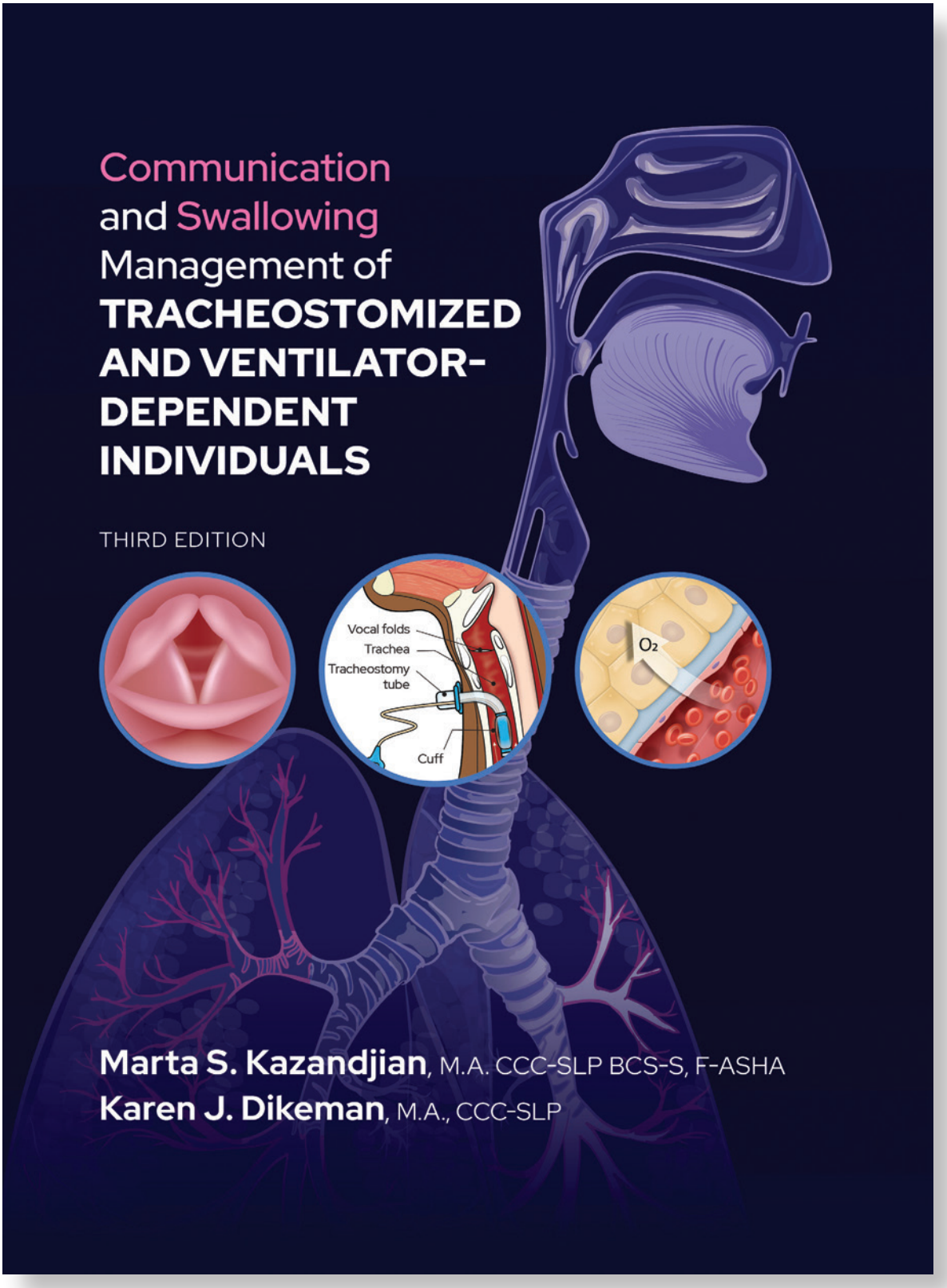
Jenny Opalinski is a practicing medical speech-language pathologist with 10 years of experience in acute care. She is a member of the interdisciplinary trach/vent weaning team at her facility. She is currently employed at CareOne LTACH, a PMV Center of Excellence. She also utilizes Respiratory Muscle Strength Training (RMST) as a part of her daily clinical practice and for research. She has interests in pursuing evidence-based practice that will enhance the care of her patients for both the areas of communication and swallowing.

Gail M. Sudderth, RRT

Gail M. Sudderth, RRT, practiced as a respiratory therapist for over 40 years. Her experience included acting as a lead therapist at a large teaching hospital with a focus on medically complex patients who required tracheostomy and mechanical ventilation. Her expertise was managing patients who were considered difficult to wean. In her role, she worked closely with the speech-language pathologists and developed training competencies for suctioning and cuff management. Ms. Sudderth had a long history of developing and co-developing web-based presentations and on-site seminars for medical professionals who care for patients with tracheostomy. She was a well-respected and invited speaker, with a history of presenting in the US and internationally at hospitals and professional medical meetings on the topic of airway and ventilator management and the application of the Passy Muir® Valve. In addition, she published articles on the importance and development of multidisciplinary airway management teams. She was a Clinical Specialist – Respiratory Therapy for Passy-Muir, Inc. for 14 years.

Cheryl Wagoner, MS, CCC-SLP, BCS-S

Cheryl Wagoner is the Inpatient Therapy Director for the Specialty Hospitals at Madonna Rehabilitation Hospitals. She was a staff SLP with Madonna Rehabilitation Hospital on the Long Term Acute Care Hospital (LTACH) unit for 14 years where she gained extensive experience working with medically complex adults with tracheostomy tubes and mechanical ventilation.



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