

Volume 6, Issue 1

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Physicians' Perspective on the Passy Muir® Speaking Valve

Evidence Based Support for Using PMV[®] In-line with Mechanical Ventilation

Effects of PMV Use In-line on Communication & Swallowing

Speaking Valve Use During Mechanical Ventilation

Clinical Hot Topic: VAP

Current Research

In-line Ventilator Application Issue



TALKOMUIR



Volume 6, Issue 1

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Welcome to Talk Muir: Addressing Use of the Passy Muir[®] Tracheostomy and Ventilator Swallowing and Speaking Valve In-line with Mechanical Ventilation

Welcome to the new Talk Muir. This publication has been restructured to provide a clinical research perspective for the safe and effective use of the Passy Muir[®] Tracheostomy and Ventilator Swallowing and Speaking Valve (PMV[®]). Each edition of Talk Muir will focus on specific topics relating to the care of patients who are tracheostomized or mechanically ventilated. It is the Editor's objective that Talk Muir will now provide readers with clinical perspectives and cutting edge research to address specific questions raised by practitioners relating to the use of the PMV.

In this new format, you will find key elements:

- Editor's Commentary an overview of the newsletter theme topic or question
- Physician's Corner a spotlight on one or two invited physicians who will write their perspective on the theme topic for that issue
- Researcher's Perspective invited researcher, who provides the latest research on the topic area, and an interview-based format with questions directly asking the researcher about his/her current and ongoing research
- Clinicians' Perspectives featuring two articles respiratory therapy and speech-language pathology
- Peer-Reviewed Published Research Studies top studies as selected by clinical professionals and non-clinical personnel working in the topic area. Studies selected based on the following criteria: study design, hypothesis, research question, relevance, and findings. Summaries of each of the top articles are featured.
- Research bibliography a bibliography of the top articles for the theme topic
- Clinical Take-home Boxes take-home clinical suggestions/therapy recommendations by respiratory therapy and speech-language pathology
- Hot Topic Box answering a key clinical question that has been a hot topic from our tech calls or clinicians

For the inaugural issue, the selected topic is: *Addressing Use of the Passy Muir® Tracheostomy and Ventilator Swallowing and Speaking Valve In-line with Mechanical Ventilation*. For patients who are mechanically ventilated, compromised communication can be emotionally taxing and may lead to miscommunication and even medical errors. Because a tracheostomy tube is placed below the vocal folds, and mechanical ventilation is typically performed with an inflated cuff, airflow does not travel upwards through the folds into the upper airway. These changes in function lead to several factors that have negative implications for the patient; however, because of the patient's medical status and need for mechanical ventilation, change to this process is often difficult and even controversial.

A bias-closed, one way, no leak speaking valve for in-line use on the ventilator is the Passy Muir Tracheostomy and Ventilator Swallowing and Speaking Valve. The PMV[®] was invented by David Muir, a ventilator dependent patient with a desire to have verbal communication. The valve functions by opening during inspiration and closing at the end of inspiration, redirecting airflow up through the vocal folds and out through the mouth and nose. This process helps to restore a more normalized physiologic process and normal functions, such as verbal communication.

Using a Passy Muir Valve in-line with mechanical ventilation requires that the cuff be completely deflated. Therein lies the basis for numerous questions raised by clinical professionals. This edition of Talk Muir is designed to address these concerns by providing the perspectives of several professionals and sharing the latest research, which provides additional evidence-based support for use of a one way speaking valve in-line with mechanically ventilated patients.

Austin aking PhD, CCC-51P

About the Editor

Kristin King, PhD, CCC-SLP has been a speech-language pathologist in a variety of settings since 1998. 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. Doctor King has published several peerreviewed 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 ISSUE: Use of the PMV in the Pediatric Population with Tracheostomies and Mechanical Ventilation, including therapeutic interventions.

We welcome suggestions and comments related to the current issue or on issues in the future. We also invite clinicians, professionals, and researchers to submit papers for review and possible publication. Contact us if you would like to be considered as a potential author for a topic, or give us your prospective if you have an interest in an upcoming topic or a suggestion for a topic.

Please email your comments, suggestions or requests to: kking@passy-muir.com



Physicians' Perspective on the Passy Muir® Speaking Valve

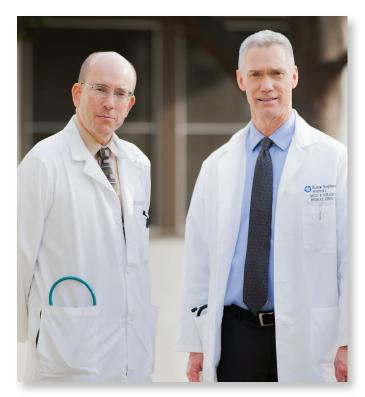
David R. Nelson, MD, Medical Director, Barlow Respiratory Hospital Scott A. Sasse, MD, Pulmonary Medical Director, Barlow Respiratory Hospital

Barlow Respiratory Hospital is a unique place to practice medicine. The hospital is small, only 60 beds on the main campus in Los Angeles. The hospital was founded in 1902 as a Tuberculosis Sanatorium and remains surrounded by nature, despite its location only a few miles from downtown. At Barlow Respiratory Hospital, our interdisciplinary staff is tight-knit and works as a team. Our patients are primarily transferred to us from intensive care units at other facilities in the surrounding area. We have developed an effective methodology for in-line use of the Passy Muir[®] Valve with mechanically ventilated patients.

From our point of view, the Passy Muir Valve offers patients a feeling that they can control their destiny. It gives the patient a sense of well-being, an ability to participate in their medical care, and restores a sense of independence.

Physiologically, in the appropriate patient, the valve improves the ability to cough and clear the airways. It reduces the chance of aspiration and provides protection by decreasing the chance of bacteria lingering above the tracheostomy.

Equally important is the psychological impact of being able to communicate. Patients on mechanical ventilators find it very difficult to communicate. They try to write, use gestures, or mouth words. Limited options for communication lead to a great deal of frustration. All of that just goes away when they can talk – when they have a voice. When the Passy Muir Valve is inserted for early intervention and use with mechanical ventilation, it makes the patient happy, and it makes the family more content. In some cases, we can insert the valve into the circuitry of the mechanical ventilation in the morning, and that very same day, the patient can pick up the phone and talk to a family member who has not heard their voice for weeks, sometimes even months.



Scott A. Sasse, MD (on left) and David R. Nelson, MD (on right)

Each of us has seen the benefit of the Passy Muir Valve. Being able to communicate needs and feelings is very beneficial. It provides patients with a different perception of their physicians. Physicians are seen as helpful to their healing process. Typically, when patients see a physician coming, they sometimes cringe, expecting something that is going to hurt – another needle or another tube. But with the Passy Muir Valve, we are able to offer our patients something of medical value that also is painless and has the benefit of lifting their spirits.

Communication is not only good for our patients, it is also good for us, as physicians. Patients can tell us what is going on with them. Both of us have a great deal of experience with using the valve and seeing its benefits. Each of us also has seen the benefit of the more aggressive use of the Passy Muir[®] Valve through early intervention with patients who are mechanically ventilated. For many, many years, we had used the Passy Muir Valve when a patient was close to finalizing the weaning process or was completely off the ventilator. In the past year and half, we have made a change in our approach to when we introduce the speaking valve.

Now, it is in our protocol to try the patient on the valve much earlier, while still on the ventilator. We are very fortunate that our team includes exceptionally experienced Respiratory Therapists and Speech Therapists. They are proactive in identifying patients who are good candidates for early introduction of the valve. Overall, both of us are convinced of the positive physiological and psychological impact of the Passy Muir Valve for our patients. Recently, we had a patient who had been on the ventilator for a few weeks. At the previous hospital, they had not tried to wean her. We inserted the valve soon after she settled in, and she was delighted. It is a joy to see the difference this makes for our patients. We see the Passy Muir Valve as an opportunity to embrace excellence in our medical practice while reclaiming a small measure of enjoyment for our patients.



Clinical Take Home: The Benefits of Patient Communication | Kristin King, PhD, CCC-SLP

The patient communication benefits observed by doctors Nelson and Sasse are consistent with the research. Studies show that return of voice through the use of a Passy Muir Valve has a material positive impact on a patient's well-being (Freeman-Sanderson, Togher, Elkins & Phipps, 2016). Patients who can participate in their care have better outcomes, whereas patients with communication issues are three times more likely to suffer a preventable adverse medical event (AHRQ 2013; Bartlett, Blais, Tamblyn, Clermont & Macgibbon, 2008). The ability to communicate with a patient also enables practitioners to obtain an accurate history, which is often considered "the most powerful diagnostic tool available to the internist" (Peterson, M., Holbrook, Von Hales, Smith & Staker, 1992). Research also indicates that patients who communicate have more effective pain management, while "[d]ifficulty communicating with health care practitioners remains a significant barrier for patients seeking pain relief and may partially explain why pain continues to be frequently undiagnosed and mismanaged" (Shea & McDonald, 2010). Patient communication is also an important component of informed consent and may prevent malpractice claims (Huntington & Kuhn, 2003). In addition, the American with Disabilities Act requires that health care practitioners provide patients with an effective means to communicate (US DOJ 2014). It is important that practitioners consider the patient communication benefits when deciding the timing of providing a PMV[®] to return a tracheostomized patient's voice.



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Evidence Based Support for Using a PMV® In-line with Mechanical Ventilation

A Researcher's Perspective

Anna-Liisa Sutt, BA, MA Speech Pathology

Kristin King, PhD, CCC-SLP, Vice President of Clinical Education and Research, Passy-Muir, Inc.

Introduction

Misconceptions exist about potential risks for harming a patient's already-compromised lungs during recovery if a speaking valve is used with patients who are mechanically ventilated, and these misconceptions tend to hinder use of speaking valves with this population. Arguments about use of a one way speaking valve during mechanical ventilation include the ideas that there are increased risks of aspiration due to cuff deflation, decreased lung recruitment because of lost ventilation with cuff deflation, and even increased risk of barotrauma because of increased lung pressures. While the purpose of mechanical ventilation is to support the respiratory system during recovery, the changes it causes in the physiologic function of the respiratory system also lead to deleterious effects on secretion management, lung function, communication, swallowing, subglottic pressure, and other parameters affecting function. Frequently, the potential risks are used as reasons to delay use of a speaking valve in-line on the ventilator; however, research does not support them. These a priori assumptions are not substantiated with research, and clinical observations have been providing anecdotal evidence that was contrary to prior teachings. Previously, there has been a paucity of research to support what has been seen clinically; however, current empirical research is demonstrating that the use of a speaking valve in-line with mechanical ventilation is promoting improved ventilation (Sutt et al., 2016) and faster weaning (Carmona et al., 2015), among other benefits.

Additionally, patient centered care focuses on patients' rights to communicate and participate in their medical care, and patients who are mechanically ventilated have compromised communication which can be emotionally taxing and may lead to miscommunication and even medical errors (Egbers et al., 2014). Because a tracheostomy tube is placed below the level of the vocal folds and mechanical ventilation typically requires the cuff be inflated, air flow does not travel upwards through the vocal folds into the upper airway. During ventilation, airflow is directed between the ventilator and the lungs for both inspiration and

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expiration. This artificial form of respiration causes many changes to the normal physiologic function of the respiratory and aerodigestive systems. Using a bias closed, one way speaking valve in-line allows airflow to be re-established through the upper airway, providing stimulation to the vocal folds and upper sensory inputs, and patients are able to phonate, verbalize, and have more normalized processes. The positive effects of restored communication for the patient who requires mechanical ventilation have been well documented. In 2016, Freeman-Sanderson et al. reported time to phonation using speaking valves in ICU patients was 11 days sooner than the control group without speaking valves, and subjects reported significant improvements in self-esteem, being understood by others, cheerfulness and quality of life.

So, for patients with mechanical ventilation we have a two-fold process to consider, the changes to the physiologic mechanics of the process of respiration, speech, and swallowing, and the patient's psychological well-being – all of which affect recovery and outcomes.

Recent research is demonstrating that in-line use of the Passy Muir[®] one way speaking valve (PMV[®]) during mechanical ventilation is facilitating both communication and improved lung function

Effects on Communication

Recent research is demonstrating that in-line use of the Passy Muir[®] one way speaking valve (PMV[®]) during mechanical ventilation is facilitating both communication and improved lung function. Sutt, Cornwell, Mullany, Kinneally, and Fraser (2015) investigated the effect of in-line speaking valves on both the duration of mechanical ventilation and time to verbal communication by collecting data on 129 patients with a mean age of 59 ± 16 years in a retrospective pre- and post-observational study, for years 2011 and 2012, using an ICU informational system and medical records. The purpose of the study was to compare tracheostomy outcomes in patients who were mechanically ventilated by investigating pre-introduction and post-introduction of in-line speaking valves. A significant difference was found for communication, with a 9 day faster implementation of verbal communication post-introduction of the speaking valve. While no difference was found for time of mechanical ventilation or time to decannulation. the authors report that no adverse events were documented in relation to the use of speaking valves in-line with this population. This study not only provides evidence that use of a speaking valve in-line provides patients with earlier access to communication, it reports that use of a speaking valve in-line did not cause any adverse effects.

A follow-up study by Sutt and Fraser (2015) analyzed data for years 2013 – 2014 to evaluate the practice of speaking valve use across ICUs, if it had continued to increase, and the impact on the standard of care. This additional analysis brought the total studied patient population across 4 years to 274 tracheostomized patients in ICU. Comparing the 2013-2014 data points to the earlier 2011-2012 data points, the authors found a significant reduction in the average number of days from tracheostomy tube insertion to return to verbal communication since the previous study. The return to verbal communication since the introduction of a one way speaking valve as a standard of care was now an average of 6 days post tracheostomy. The patient population using speaking valves had significantly increased with the implementation of a protocol for use of speaking valve in-line, from 0% in 2011 to 70% in 2014. The authors report that overall, 75% of their patients with tracheostomy who are mechanically ventilated are now communicating verbally. They also report that the use of the speaking valve and the ability to speak has not been associated with any deterioration of any measurable ventilatory or respiratory outcomes in these patients.

Effects on Lung Function

While these studies primarily reported findings related to communication, Sutt, Caruana, Dunster, Cornwell, Anstey, and Fraser (2016) also investigated the specific effects of in-line use of a one way speaking valve on lung function with patients who are mechanically ventilated. The purpose of this study was to assess end expiratory lung impedance (EELI) and standard bedside respiratory parameters before, during, and after speaking valve use in patients with tracheostomy who were weaning from the ventilator. This prospective observational study was conducted on 20 consecutive patients and used Electrical Impedance Tomography (EIT) to monitor EELI. EIT is a non-invasive, radiation free, imaging tool that measures end expiratory lung volumes. The authors report that use of the speaking valve in-line significantly increased EELI while the valve was in place, and the effect was maintained for at least 15 minutes after removal of the valve. The authors were able to measure and demonstrate that the lungs were more involved in respiration with the speaking valve in-line than without a speaking valve. The authors' findings demonstrated that speaking valve use did not cause derecruitment of the lungs during ventilator weaning; subsequently, the authors suggest these findings indicate that use of a one-way speaking valve may actually facilitate lung recruitment during and after speaking valve use. The authors also found that respiratory rate and EtCO₂ decreased significantly during PMV use with oxygen saturations and heart rate unchanged.

Effects on Respiratory Mechanics

Sutt, Cornwell, Caruana, Dunster, and Fraser (2015) also investigated the use of an in-line speaking valve on respiratory mechanics. This research was initiated secondary to the questions that have arisen related to concerns with derecruitment and atelectasis that may develop with prolonged weaning from mechanical ventilation. The authors studied 18 consecutive patients with tracheostomy who were weaning off ventilation and able to tolerate a speaking valve for 30 minutes. The investigators used EIT and respiratory inductance plethysmography (RIP), which measures abdominal-chest movements ratio, for a total of one hour. The authors also collected oxygenation, end tidal carbon dioxide, respiratory rate, heart rate, and airway pressures. The findings indicated universal improvement in lung recruitment with the speaking valve pre- and post-use as compared to baseline measurements. Significant improvement in abdominal

mobility was measured with RIP when the speaking valve was in use. The authors suggest this finding represents an increase in diaphragm involvement in breathing when the speaking valve is in-line. The authors also reported a significant improvement in health related communication for both patients and nursing staff. The authors interpreted these findings to mean that speaking valves are a safe option for enabling verbal communication when patients are on mechanical ventilation. They also reported that improved lung recruitment and diaphragm involvement may improve overall respiratory mechanics and lead to more rapid liberation.

Summary

These recent studies are demonstrating that use of a one way speaking valve in-line with patients who are mechanically ventilated not only provide psychosocial benefits by increasing communication and affecting self-esteem in a positive manner, they also are investigating the physiologic effects on the respiratory system. Current research findings support the previous anecdotal evidence that patients on mechanical ventilation benefit from having access to verbal communication and that using a speaking valve in-line does not cause detrimental effects on lung recruitment or other physical parameters, such as heart rate or oxygen saturations. Sutt et al. (2015, 2016) have begun a series of research studies that demonstrate improved lung function and increased diaphragmatic involvement in respiration without deleterious effects. Freeman-Sanderson et al. (2015, 2016) have investigated the impact on communication and well-being with the additional findings for improved quality of life of ICU patients. In the past the paucity of research for in-line use of valves contributed to the difficulty in having evidence-based practice for use of a Passy Muir[®] one way speaking valve in-line. However, the current research studies provide strong supporting evidence for both the physiologic improvements and the patient's well-being.

Researcher's Perspective

In considering the current trends in research for investigating the use of Passy Muir[®] Valves in-line with patients who are mechanically ventilated, Anna-Liisa Sutt (first author on many of the cited studies) provides her insight as a researcher into these trends:

1 As a researcher who focuses much of her research on a population of patients who are mechanically ventilated and who, historically, received a handsoff approach with use of speaking valves, what caused you to pursue this line of research? Starting work in a cardiothoracic ICU where all of my tracheostomised patients were mechanically ventilated, it was devastating to see that all of them were left voiceless. Some of them fully alert, eating and drinking with their tracheostomy cuffs inflated, but left in silence. It was obvious that something needed to be done about it. With Critical Care Research Group (CCRG) on site with all the necessary equipment and expertise, I was in a very lucky situation where setting up a research project was relatively easy with all the help I needed right here at the hospital.

2 Frequently, the use of speaking valves in-line on the ventilator are not pursued for patients who are mechanically ventilated. What do you believe is the biggest misconception about using the valve in-line?

Based on my personal experience in an Australian critical care setting, I believe it is the opinion that the air-leak created by cuff deflation needed for PMV[®] use may cause derecruitment of the patients' lungs. The studies in the area of mechanical ventilation put a lot of focus on recruitment manoeuvres and weaning strategies, so anything that could potentially act in the opposite direction, is of course frowned upon. Lack of physiologic data has not been able to support us thus far, either.

Another misconception (though less frequent in my experience) is the fear of aspiration with a deflated cuff.

3 In your research addressing lung recruitment, you have found that with the valve in-line while mechanically ventilated, as measured with EIT, that patients demonstrate increased lung volumes. What are the implications for weaning and recovery?

EIT data showed us that there was increased endexpiratory lung impedance (EELI) during and post PMV use. EELI has been highly correlated with endexpiratory lung volumes (EELV) in other studies, which is why we are referring to it as increased EELV during and after PMV use. End of expiration is when the lungs are at most risk for collapsing. If we are seeing increased EELV, then we can presume that the lungs are kept open better, and are therefore less likely to collapse/develop atelectasis. At the same time, we need to be mindful of potential over-distension in some lung areas which can happen in case EELV gets too big. The perfect midway somewhere between the two is what works best for lung recovery and weaning. 4 Your research clearly demonstrated an increase in lung volumes with the valve in-line, could you explain why having the valve in-line provided this improved ventilation as compared to not having the valve in-line?

My research can't directly answer this question. There may be several reasons for the increase in EELI seen with PMV[®] use. One of the most likely reasons is the restored physiological PEEP – patients being able to exhale through their upper airway again may be able to control the resistance to expiratory airflow, thereby maintaining more air in the lungs at the end of expiration. At the same time – a cuffed tracheostomy tube occupies a significant part of the airway that the patients wearing a PMV have to breathe around. So it is not just the physiological PEEP, but also some added resistance by the tube itself during exhalation, which may also contribute to increased EELI.

Similar studies are needed in different modes of ventilation to further clarify the role of positive vs negative pressure ventilation and the diaphragm on lung mechanics and recovery.

5 You've now found that there is increased lung recruitment and lung volumes with use of the Passy Muir[®] Speaking Valve in-line, are you able to provide more information about what areas of the lungs are involved in this recruitment?

I am in the process of finalizing this part of data write-up for the next manuscript. Preliminary data is certainly suggesting a quite a uniform increase in EELI across the lung sections.

6 What is the next step in your research?

There are too many next steps to define just one. I am keen to finalise the analysis on ventilation distribution with the PMV use, and then perhaps look at valve use with other ventilation modes (i.e. volume controlled ventilation) and different patient cohorts.

7 What future directions need to be pursued in research as related to patients who are mechanically ventilated?

As lung physiology is quite different in different types of disease processes, similar studies are needed in different ventilation modes and some other patient groups, such as patients with obstructive lung disease. I think there is also room for a few benchtop studies looking at airway pressures (including PEEP) with and without the valve in different ventilation modes. 8 As a researcher and speech pathologist, who has been working with patients who are mechanically ventilated, what do you consider to be the strongest evidence and support for why a Passy Muir Valve should be used in-line with patients who are mechanically ventilated? Why pursue early intervention?

I think the strongest evidence and support is the patients themselves. We are here for the patient, for better care for the patient. Intensive care has long been about survival. But often ... 'The quality of life is more important than life itself' (Alexis Carrel). *Communication matters.* And the patient is the best advocate for it. We just need to make sure we do it safely, without detrimentally affecting the other organs. We know from research that voicelessness and lack of control are big issues in ICU, and can lead to poor ICU outcomes, short and long term. The earlier the patients are able to have a say in their care and feel that they are actively involved, the better the outcomes, one would think. Much more research is needed in the area, but we have a few solid bricks laid for the structure.

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Effects of PMV[®] In-line with Mechanical Ventilation on Communication and Swallowing

A Speech-Language Pathologist's Perspective

Maribel Ciampitti, MS, CCC-SLP

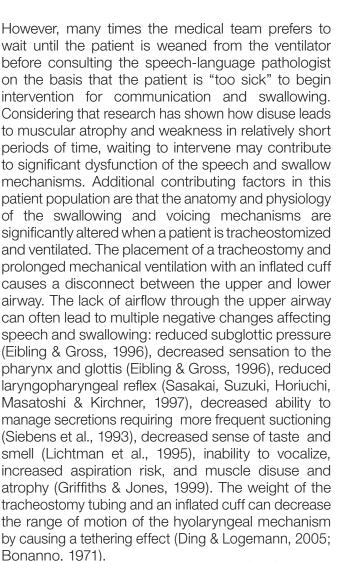
Annually, more than 100,000 patients in the United States experience medical events that require a tracheostomy, with 24 percent of those necessitating mechanical ventilation (Yu, 2010). It is estimated that by the year 2020, there will be over 600,000 patients requiring prolonged mechanical ventilation (Zilberberg, 2008). Most vented patients are on prolonged bedrest during hospitalization. In intensive care units across the country, efforts are being made to implement early mobility programs as there is significant evidence indicating that many patients in intensive care units on prolonged mechanical ventilation experience a marked decline in functional status (Spicher, 1987). After one week of bedrest, muscle strength may decrease by as much as 20 percent with an additional loss of 20 percent each subsequent week of bedrest (Perme, 2009; Sciaky, 1994). Why is this significant to speech-language pathology?

The loss of strength extends to the muscles of respiration and the oropharyngeal musculature, which affects communication and swallowing (Griffiths & Jones, 1999). Muscle weakness is an independent predictor of pharyngeal dysfunction and symptomatic aspiration. Patients with muscle weakness often have greatly reduced cough strength and poor control over their swallowing and upper airways (Griffiths & Jones, 1999). The implementation of early mobility and rehabilitation in the fields of physical and occupational therapy has shown positive outcomes in ICU patients (Adler, 2012). The same principles used to promote strength for mobility can be applied to strengthening the oropharyngeal and respiratory musculature to improve swallowing and communication (Burkhead et al., 2007). Two examples of these principles would be the overload principle, where physical capacity is challenged, and the principle of "specific adaptation to imposed demands" when the exercise is linked to the demand and function of the muscle (Trees, Smith, Hockert, 2013). The therapeutic intervention plans developed for voicing, communication, or swallowing often reflect these principles, addressing the muscles involved by using functional tasks which also directly address the demand and function of the muscles.

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Furthermore, patients on mechanical ventilation can experience discoordination of breathing, which can negatively impact speech and swallowing (Pringent et al., 2011).

The effects of tracheostomy and vent dependence are not just physical. For patients, the loss of the ability to communicate their everyday needs can lead to increased psycho-emotional distress, (Khalaila et al., 2011), including anxiety and depression (Chen et al., 2011). It robs patients of the ability to participate in their own care and decision making process. Studies have shown that the Passy Muir® Valve used in-line can, in many cases, restore early verbal communication to vent-dependent patients, facilitate the care given by healthcare personnel, enhance their mental outlook, and allow participation in their own care without observed complications (Sutt et al., 2015; Manzano et al., 1993; Passy et al., 1993). Communication is not just a patient right but a basic and important human right. Efforts should be made to facilitate the communication needs of ventilator dependent patients who are in both a vulnerable and difficult position.

The speech-language pathologist (SLP) is in a unique position to provide early intervention and rehabilitation to patients who are tracheostomized and on mechanical ventilation via early assessment for the use of a bias closed, no leak speaking valve (Passy Muir Valve) for in-line use with the ventilator. Early intervention by the SLP should begin by identifying patients on mechanical ventilation who are candidates for trials using the Passy Muir Valve (PMV®). The benefits of early assessment and implementation with the PMV are many. First and foremost, use of the PMV helps to restore the physiology of the upper airway to its more "normal" state by returning airflow through the upper airway during exhalation. This restoration of airflow to the upper airway allows evaluation of airway patency, vocal cord function, secretion management, and communication skills. In many cases, voicing is restored, allowing the patient to communicate basic needs and participate in their daily care. The restoration of communication also allows the SLP to conduct more thorough speech/ language and cognitive assessments, which lead to earlier therapeutic intervention for patients who may have experienced other co-morbidities, such as stroke or traumatic brain injury. Without verbal communication or vocalizations, assessment of speech and language deficits would otherwise be very limited for patients on mechanical ventilation. With early assessment comes early therapeutic intervention and planning for care.

Communication is not just a patient right but a basic and important human right.

Swallow function is often negatively affected in patients who are tracheostomized and on mechanical ventilation. It is estimated that 50-87% of patients with tracheostomy aspirate, including silent aspiration (Elpern et al., 1987, 1994, 2000). Research suggests that tracheostomy speaking valves may positively impact swallowing function and rehabilitation (Blumenfield, 2011). Research also has demonstrated that early implementation of a swallowing rehabilitation program is feasible for patients on mechanical ventilation (Rodrigues et al., 2015). Physiologically, the bias closed, no-leak valve design of the PMV allows for restoration of subglottic air pressure which has been shown to decrease or prevent aspiration in some patients (Dettelbach et al., 1995). Implementation of the PMV in-line allows for more reliable swallow assessment both at the bedside and with instrumentation. Reliability increases with the return of functions such as cough, throat clear, and voicing. With the PMV in-line on mechanical ventilation, the SLP is able to evaluate the integrity of the aerodigestive tract and more thoroughly assess potential risk factors related to the function of the vocal cords, cough strength, and secretion management abilities. Furthermore, the redirection of airflow provides sensory stimulation to the oropharynx and can improve management of secretions, as well as improve taste and smell (Lichtman et al., 1995).

By providing earlier intervention and evaluation, many patients are able to progress safely to an oral diet, even while on mechanical ventilation. For those patients with dysphagia that are not candidates to begin an oral diet, PMV use can be instrumental in the swallow rehabilitation process. Almost all swallowing rehabilitation techniques require the restoration of subglottic pressure to achieve effective results. Almost all oral motor exercises, pharyngeal exercises, swallow maneuvers (such as the Mendelsohn and Supraglottic Swallow), and respiratory muscle strength training require a closed system and subglottic airway pressure. The rehabilitation process may begin with tasks as simple as getting the patient to relearn breathing through the upper airway again and working on managing secretions during PMV trials.

Many patients on prolonged mechanical ventilation also have decreased volumes and poor expiratory strength, which affect swallowing and may place a patient at higher aspiration risk (Gross et al., 2003). PMV[®] use allows patients to participate in respiratory muscle strength training, which has been shown to improve voicing and swallow function (Sapienza & Trocher, 2012). Although many patients successfully tolerate PMV trials on initial attempts, not all tracheostomized patients will be immediately successful. Furthermore, not all swallowing function is improved by tracheostomy tube occlusion; therefore, other variables will need to be considered and evaluated (Donzelli et al., 2006). It is important to work with a multidisciplinary team to troubleshoot potential issues that may affect PMV tolerance, such as trach tube size, upper airway pathology, and underlying medical issues or co-morbidities, so that patients receive the best standard of care and are set up for success with the PMV.

Healthcare professionals who work with medically complex patients on mechanical ventilation face many challenges. Tracheostomized and vented patients are best served by multidisciplinary teams including physicians, respiratory care practitioners, nurses and speech-language pathologists. Other important team members include dieticians, physical and occupational therapists, psychologists, and social workers. The research evidence suggests that early intervention with the Passy Muir[®] one-way valve on mechanical ventilation may lead to improved outcomes. Research has suggested reduced weaning times, improved communication and swallow function, reduced hospital length of stays, reduced cost of care, and overall improvement in the quality of life (Speed & Harding, 2013; Cameron et al., 2009). Studies have shown that waiting until the patient is weaned to intervene can contribute to disuse and atrophy of the speech and swallowing mechanisms leading to significant communication and swallowing deficits. 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 Passy Muir® Valve, in-line during mechanical ventilation, increases the opportunity for patients to speak, swallow, and participate in direct therapy sooner and has the potential to reduce anxiety, wean times, and lengths of stay. Delayed intervention could potentially complicate efforts to liberate patients from the ventilator, as prolonged ventilation carries risks.

Practices in the timing of speech-language pathology intervention for patients on mechanical ventilation vary across medical settings. Because early intervention addressing communication and swallow function has been shown to have a significant impact on patient outcomes, efforts should be made by speech-language pathologists to evaluate current protocols in ICUs and other medical settings to promote early intervention for patients with transient or chronic vent dependency.

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Speech-Language Pathology Therapy Chart | King, Ciampitti

Swallow Impairment	Therapeutic Intervention	Adaptation for Trach/Vent Patient
Secretion Management	 PMV[®] trials to allow airflow and sensory stimulation to upper airway 	 Train inhaling/exhaling through semi-occluded airway (straws) for low level patients
	2. RMST (Respiratory Muscle Strength Training)	2. Use various IMST/EMST devices on the market to strengthen respiratory system
Low Lung Volumes	IMST (Inspiratory Muscle Strength Training) Supraglottic Swallow	Requires PMV use to engage entire respiratory system, restore subglottic pressure
Weak Cough Strength	Cue patient to cough/clear own secretions EMST (Expiratory Muscle Strength Training)	Requires PMV use to restore subglottic airway pressure
Decreased Vocal Cord Closure	Supraglottic Swallow/Voluntary Breath Hold Adduction Exercises with resistance Sustained phonation	Requires PMV to establish a closed system, restore subglottic pressure
Reduced Laryngeal Elevation	Falsetto Exercises Mendelsohn Maneuver	Requires PMV to establish a closed system, restore subglottic pressure
Reduced Hyolaryngeal Excursion	Super-Supraglottic Swallow	1. Both require restoration of subglottic pressure-place PMV
	Shaker Maneuver	2. Shaker: Place PMV to restore pressure, do not lay patient completely flat, ensure trach does not displace or occlude
Weak Pharyngeal Wall Construction	Effortful Swallow Masako	Requires PMV to close system, restore subglottic pressure
Reduced Cricopharyngeal Opening	Shaker Maneuver Mendelsohn Maneuver	Shaker: Place PMV to restore pressure, do not lay patient completely flat, ensure trach does not displace or occlude

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

A Respiratory Therapist's Perspective

Gail M. Sudderth, RRT

The inability to communicate during periods of mechanical ventilation (MV) can increase psychoemotional distress (Egbers, Bultsma, Middlekamp, & Beoerma, 2014) and has been associated with depression and post-traumatic stress disorder (Freeman -Sanderson, Togher, Elkins & Phipps, 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 aero digestive 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, Díaz, Alonso, Guarasa, Martínez, & López, 2015), promote alveolar recruitment (Sutt, Cornwell, Mullany, Kinneally & Fraser, 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

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, O'Brien, Reid, Brooks & Crowe, 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, Rosenbek, Davenport, & Sapienza, 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, Lynch, Wilson, Nicholson & Wallace, 2016; Hoit, Banzett, Lohmeier, Hixon, & Brown, 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 cmH₂0 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, Lynch, Wilson, Nicholson, and Wallace (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... 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, Cornwell, Mullany, Kinneally, and Fraser (2016) reported improved lung recruitment when using the Passy Muir® speaking 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 inline 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 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

Clinical Hot Topic | King

Ventilator-Associated Pneumonia (VAP)				
Definition	Develops 48 hours or longer after mechanical ventilation is given by means of an endotracheal tube or tracheostomy Results from the invasion of the lower respiratory tract and lung parenchyma by microorganisms Intubation compromises the integrity of the oropharynx and trachea and allows oral and gastric secretions to enter the lower airways	Sensitivity and specificity in diagnosing VAP is very poor (less than 33%) due to tracheobronchial secretions in mechanically ventilated patients which are seldom caused by pneumonia; even more difficult to diagnose in patients with ARDS		
Population	27% of critically ill patients; commonly - ICU patients			
How common?	Pneumonia is 2nd most common	86% are termed VAP		
Risk Factors	Underlying heart and lung disease, neurologic disorder, trauma, flat HOB, aspiration BEFORE intubation			
Causes	Microorganisms that are resistant; thought to exist in the mucosal tissues of the bronchi but become active with intubation	Typically, infection begins shortly after intubation (48-72 hours)		
Preventions	Hand washing, sterile techniques with invasive procedures, isolation, limiting sedation, increase HOB	Aggressive weaning protocols; early tracheostomy; good oral hygiene; reduced use of oropharyngeal and nasopharyngeal feeding tubes		

TAKE HOME

VAP occurs with oral intubation and typically within 48-72 hours. Cuff use and deflation with a tracheostomy is not associated with VAP. VAP is associated with introduced bacteria during invasive procedures (such as intubation) or already exists in the tissues and becomes active due to a suppressed immune system.

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FAQs about Ventilator Associated Pneumonia. https://www.cdc.gov/HAI/vap/vap_faqs.html

Current Research Related to Mechanical Ventilation and Speaking Valve Use

Megan Brogan, MS, CFY-SLP, Kristin King, PhD, CCC-SLP

Freeman-Sanderson, A.L., Togher, L., Elkins, M.R., and Phipps, P.R. (2016). Quality of life improves with return of voice in tracheostomy patients in intensive care: an observational study. *Critical Care Medicine*, 33:186, (Epub 2016 Jan 13).

Current research shows an overwhelming association of negative emotions, including fear, anxiety and depression with patients admitted to the intensive care unit (ICU). Statistics report up to 75% of patients report anxiety and 40% report depressive symptoms following admission to ICU (Nelson et al. 2001).

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These investigators conducted a prospective, observational study of 22 patients in a tertiary ICU, to evaluate the effects of vocal communication on mental and physical wellness. The study measured patient-reported change of mood, communication-related quality of life, and general health status with return of voice among mechanically ventilated tracheostomy patients admitted to the ICU. Daily evaluations were conducted to assess patients' quality of life in relation to communication, and weekly evaluations were conducted to assess their general health status. All participants had undergone a tracheostomy and experienced voicelessness during mechanical ventilation. Patients progressed through cuff deflation, assessment/management of swallowing, and a communication assessment, which included implementation of the Passy Muir® speaking valve.

Results collected from both daily and weekly data of patients in the ICU concluded that patients' self-esteem and mood directly coincided with regaining function of voice after the tracheostomy; specifically, improvement was seen in the ability to be understood by others and the patient's cheerfulness. The authors also suggested that functional use of the voice may be associated with a positive change in health and rehabilitation, however, the authors recommend that more research is needed to investigate this relationship.

Sutt, A., Caruana, L.R., Dunster, K.R., Cornwell, P.L., Anstey, C.M., and Fraser, J.F. (2016). Speaking valves in tracheostomised ICU patients weaning off mechanical ventilation - do they facilitate lung recruitment? *Critical Care, 20*: 91. doi:10.1186/s13054-016-1249-x

Research has shown that patients who require positive pressure ventilation through a tracheostomy tube are unable to phonate due to the inflated tracheostomy cuff (Grossbach, Stranberg, Chlan, 2011). Use of a speaking valve with patients who are mechanically ventilated has been inhibited due to the concern that there is potential risk of harming the patients' already-compromised lungs during their recovery duration in the ICU.

To further assess the effects of speaking valve use on phonation, researchers Sutt et al. conducted a prospective observational study of 20 consecutive tracheostomized patients in the cardio-thoracic adult ICU, all weaning from mechanical ventilation while also using a Passy Muir Speaking Valve. The study evaluated End Expiratory Lung Impedance (EELI) and standard bedside respiratory parameters of these patients, before, during and after the use of a Passy Muir Speaking Valve.

Results from the study yielded important information regarding the potential for positive effects of in-line speaking valve use during the weaning process from a ventilator. An increase in EELI was observed following use of the Passy Muir bias closed position speaking valve. EELI was also observed to maintain and further increase for at least 15 minutes following the removal of the speaking valve from the ventilation circuit. These findings suggest there to be no evidence of significant de-recruitment of the lungs from use of the speaking valve while weaning from mechanical ventilation. Speaking valve use resulted in a reduced respiratory rate and reduced end-tidal CO_2 when used in tracheostomized cardiothoracic ICU patients weaning from mechanical ventilation.

Fernandez-Carmona, F., Diaz, M.A., Alonso, E.A., Guarasa, I.M., Lopez, P.M., and Castellanos, M.A. (2015). Use of speaking valve on preventing respiratory infections, in critical traqueostomized patients diagnosed of dysphagia secondary to artificial airway. edisval study. *Intensive Care Medicine Experimental*, *3*(Suppl 1):A936. http://www.icm-experimental.com/content/3/S1/A936

Research has demonstrated that patients with prolonged use of tracheostomized mechanical ventilation have a high prevalence of dysphagia and respiratory infections. The use of speaking valves allows for re-establishment of the patient's upper airway, facilitating rehabilitation from these dysfunctions, as well as recovery of deglutition and phonation. This article used a randomized multicenter controlled clinical trial to determine the usefulness of a speaking valve in preventing respiratory nosocomial infections in critical tracheostomized patients diagnosed with dysphagia secondary to artificial airway.

The study included a randomized selection of speaking valve use for 27 patients (+18 years) on mechanical ventilation with a diagnosis of dysphagia secondary to an artificial airway, 19 of whom were included in the final data analysis. The use of the speaking valve was implemented during the mechanical ventilation weaning-decannulation phase while in ICU. Results from the study concluded patients with speaking valve use:

- 1. Were decannulated, on average, 2 days prior to the non-speaking valve group.
- 2. Displayed decreased incidence of respiratory infectious complications and mortality as compared to the non-speaking valve use group. The mortality rate was 0 for patients using the speaking valve and 3 for patients without use of the speaking valve.

As this was an Edisval study, the authors continue to collect data on both groups.

Rodrigues, K.A., Machado, F.R., Chiari, BM., Rosseti, H.B., Lorenzon, P., and Goncalves, MIR. (2015). Swallowing rehabilitation of dysphagic tracheostomized patients under mechanical ventilation in intensive care units: a feasibility study. *Revista Brasileira de Terapia Intensiva, 27*(1): 64-71.

A prospective, non-controlled, intervention study was conducted to evaluate the effects of early identification and implementation of swallowing rehabilitation in tracheostomized patients with mechanical ventilation, recovering from dysphagia. The study assessed 14 stable patients from 7 different intensive care units, all under mechanical ventilation for at least 48 hours, following 48 hours of tracheostomy.

The patients participated in a swallowing rehabilitation program with use of a Passy Muir[®] speaking valve in every rehabilitation session. The mean duration of the rehabilitation program was 12.4 ± 9.4 days, with 5.0 ± 5.2 days under mechanical ventilation. The sessions consisted of a variety of therapeutic strategies, including mobility exercises, sensory motor integration, and swallowing maneuvers, all implemented to restore swallowing function. Patient progress was assessed with an oropharyngeal structural score, swallowing functional score, and an otorhinolaryngological structural and functional score, which were collected both prior to and following swallowing therapy.

All participant scores positively reflected significant improvement following swallowing therapy. Out of the 14 individuals included in the study, 11 patients made enough progress within just 4 days of initiation of swallowing therapy to receive oral feedings during the duration of their stay in the intensive care unit. While this study was conducted on a limited population, it successfully identified and demonstrated the feasibility of early implementation of a swallowing rehabilitation program for patients under mechanical ventilation with a Passy Muir Speaking Valve in use.

Egbers, P.H., Bultsma, R., Middelkamp, H., and Boerma, E.C. (2014). Enabling speech in ICU patients during mechanical ventilation. *Intensive Care Medicine, 40*: 1057 – 1058. doi:10.1007/s00134-014-3315-7

In this letter to the editor, the authors address the significant impact that mechanical ventilation has on the psycho-emotional function of patients in the ICU. According to research, the inability to speak during mechanical ventilation increases psycho-emotional distress for patients during ICU treatment and is more prominent in patients with a prolonged weaning period (Khalaila et al., 2011). The purpose of their letter is to encourage intensive care personnel to develop weaning protocols that include the use of a one way speaking valve, specifically the Passy Muir[®] Valve, to help with communication and weaning. In supporting their argument, they share the results from a 2013 study which measured outcomes during a weaning protocol using the one way Passy Muir Speaking Valve with mechanical ventilation.

In 2013, Egbers at al. conducted a study to evaluate the effects of cuff-deflated mechanical ventilation, in combination with a high flow non-invasive ventilator and a one-way tracheostomy speaking valve, on the speech of 24 tracheostomized patients in a mixed medical-surgical ICU. To allow expiratory flow to pass through the oropharyngeal route, a Passy Muir Speaking Valve was implemented to enhance speech.

Air leakage was present within 24 hours after the tracheotomy procedure after deflation of the cuff. Invasive pressure support ventilation was replaced by a BiPAP mode with a non-invasive ventilator (BiPAP Vision, Philips, Best, the Netherlands) at equal ventilator settings. Implementation of the BiPAP setting resulted in all 12 patients being able to speak within the first day. The quality and duration of speech was measured to improve over time with a median time, from the beginning of speech to the end of mechanical ventilation, being 12 (+/-) 6 days. Effective weaning from mechanical ventilation was achieved in all patients by progressive intervals of CPAP.

The study concluded that patients' speech following difficult weaning of tracheostomies in the ICU may effectively be restored by cuff-deflated non-invasive BiPAP ventilation in combination with use of a Passy Muir Speaking Valve.

Hoffman, L., Bolton, J., and Ferry, S. (2009). Passy Muir Speaking Valve Use in a Children's Hospital: An Interdisciplinary Approach. *Perspectives*: ASHA, 76-86.

The general purpose of a tracheostomy tube is to compensate for respiratory function via mechanical ventilation to overcome deficits of the pediatric patient's airway. While this is extremely important for the child's health, it also creates potential developmental deficits if used on a long-term basis. During exhalation, the tracheostomy tube redirects air away from the vocal folds making phonation very difficult to produce. In the young pediatric population, research has shown that the presence of a tracheostomy tube can interfere with the development of early communication interactions and subsequent speech and language development (Jackson & Albamonte, 1994).

To avoid detrimental development during implementation of a tracheostomy tube in the pediatric population, speaking valves can be used to restore speech function and promote appropriate development. According to the authors, the Passy Muir Speaking Valve (PMV[®]) is used "almost exclusively" at the The Children's Hospital of Philadelphia (CHOP). While speaking valves are used in both the adult and pediatric populations, successful use often proves to be more difficult in the pediatric population. Infant and pediatric tracheal size differs in proportion from the mature airway. Pediatric and infant patients have small airways requiring smaller, yet tighter fitting tracheostomy tubes, reducing the available air leak around the tracheostomy tube necessary for speaking valve success (Jackson & Albamonte, 1994). The PMV is fitted to promote successful function of airflow for both adult and pediatric patients.

The authors also review the effects of the PMV on restoring subglottic pressure to decrease risk of aspiration. Evidence suggests the key mechanism responsible for aspiration is decreased subglottic air pressure, which can be restored with use of a speaking valve (Suiter et al.). Another concern of long-term use of tracheostomy tubes is dysfunctional or paradoxical true vocal fold movement. The authors suggest that current research findings report that long periods of time without airflow around the vocal folds also may result in increased prevalence of dysfunctional or paradoxical true vocal fold movement (Iskowitz, 1998). The PMV is designed to allow for maximal redirection of air around the tracheostomy tube and over the vocal folds during exhalation at the resting-closed position. This design benefits the patient by providing opportunities for vocalization and speech that resembles a normal pattern (Kaut, Turcott, & Lavery, 1996).

The authors write in conclusion that interdisciplinary collaboration is essential for pediatric patients to receive optimal benefit from the PMV. The authors state that with the collaboration of the unique skills of speech-language pathologists, respiratory therapists, physicians, and nurses, a systematic and safe method for identifying, evaluating, and implementing successful use of the PMV can be achieved.

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