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Treatment Intervention Issue

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Documenting Care of Patients with Artificial Airways

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ARTICLES LEGEND



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

Treatment Interventions for Patients with Tracheostomy and Mechanical Ventilation

Welcome to this issue of *Aerodigestive Health*. The focus of this publication is to provide education and clinically relevant information for the safe and efficacious use of the Passy Muir[®] Tracheostomy & Ventilator Swallowing and Speaking Valve (PMV[®]). Each edition of *Aerodigestive Health* provides articles and other resources on the care of patients who are tracheostomized, with or without mechanical ventilation. It is the editor's objective that *Aerodigestive Health* 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 issue, you will find these key elements:

- Editor's Commentary An overview of the publication topic.
- Healthcare Practitioners' Perspectives Articles by healthcare professionals on clinical issues.
- Peer-Reviewed, Published Research Studies Top studies with summaries of each featured article.
- Research Bibliography A bibliography of the recent research related to treatment interventions and care of patients with tracheostomies.
- Clinical Take-home Boxes Relevant clinical information for healthcare practitioners, including protocols.
- Special Supplement Special section on considerations for the pediatric patient (infants) with a tracheostomy.

For this issue, the primary focus is **Treatment Interventions for Patients with Tracheostomy and Mechanical Ventilation**. Working with patients with tracheostomy and mechanical ventilation, questions often arise regarding treatment interventions and how to determine best practices. When considering this medically complex patient population, determining appropriateness for intervention and the type of interventions to be provided can be a daunting. The first step is understanding what is occurring due to the tracheostomy, mechanical ventilation, and diagnoses.

When a patient receives a tracheostomy, an incision (either surgical or percutaneous) is made to place a tracheostomy in situ. With the placement of a tracheostomy tube, several immediate effects occur. The tracheostomy tube is a means for the patient to inhale and exhale through the tube to

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provide improved respiratory function and support. However, placement of the tube leads to other changes. An open tracheostomy tube changes the direction of airflow, with airflow now being in and out through the tube and bypassing the mouth and nose (when the cuff is inflated). This change in directional airflow negatively affects smell and taste, voicing, swallow function, subglottic pressure, lung recruitment, positive airway pressure, secretion management, cough effectiveness, and more. One of the more impactful changes is the loss of the pressurized system that is the human body. With an open tracheostomy tube, pressure regulation and the use of pressure for functions such as trunk support and postural control may be impaired.

When considering a treatment plan for a patient with a tracheostomy, a first step is to restore the more normal closed system and to restore the ability to regulate pressure. A primary means for closing the system is to use the Passy Muir Tracheostomy & Ventilator Swallowing and Speaking Valve (PMV[®]), a bias-closed position, no-leak valve. Using the Valve allows a patient to breathe in through the tracheostomy tube but out through the upper airway (mouth and nose). The Valve works by closing at the end of inspiration, which redirects airflow upwards through the vocal folds and upper airway. Research has shown that this redirection of airflow assists with improving secretion management, increasing sensory awareness, improving swallowing, improving communication, restoring the pressurized system, and restoring natural physiologic PEEP (positive end-expiratory pressure), among other benefits.

This issue of *Aerodigestive Health* brings together a multidisciplinary perspective that presents considerations for treatment interventions. These interventions touch on both how to use the Valve and what therapies to consider. The variety of healthcare professionals participating in this issue provides a strong representation of multidisciplinary care for both pediatrics and adults. Their knowledge and skills combine to enlighten the reader on how to establish early interventions in the intensive care units (ICUs), including the neonatal intensive care unit (NICU), and to transition patients from the ICU to other levels of care and to home. The focus is treatment interventions and documentation.

These articles address the impact that is observed when using a PMV for closing the system and restoring more natural airflow through the upper airway. The primary consideration is that once the system is restored to a more normal pressurized system, then the therapy considerations revert to standard practices for the identified issues. What this means is that once the system is closed, if the patient has poor respiratory support for speech, then initiating therapies that address respiratory function would be appropriate. If a patient demonstrates voicing issues, voice therapy may be initiated and so on.

Considerations for early intervention and initiation of therapy in the ICU is discussed by Buffy Buchannan and Shane Harper. Hao Chin and Rachel dela Rosa present a case study specific to ventilator management and weaning considerations. Another option to assist with weaning, voicing, and swallowing would be instituting respiratory muscle strength training, discussed by Jenny Opalinski and Kaitlyn Hanley, or to begin interventions early in the recovery process such as working with disorders of consciousness as presented by Ashley Lopez and Marilouise Nichols. Working with these patients would not be complete without appropriate documentation and special considerations for this patient population, which is reviewed by Faith Parnell.

This issue also includes a special, supplemental section with two articles addressing pediatric considerations. With the esteemed Catherine Shaker, MS, CCC-SLP, BCS-S and Laura Brooks, MS, CCC-SLP, BCS-S each providing answers to commonly asked questions about the care of infants with tracheostomy, these two articles discuss the potential negative impact of an open tracheostomy tube on development and feeding/swallowing and how closing the system restores pressures that are critical to function. They discuss special considerations for the NICU and when working with infants. These two articles provide insightful discussion to enhance the care of this especially fragile patient population.

The primary take-away from this issue is that the earlier we provide treatment interventions with these medically complex patient populations, the sooner the many benefits begin, both for the patient and their recovery.

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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*.

No Need to Read Between the Lines: Documenting Care of Patients with Artificial Airways

Faith Purnell, MS, CCC-SLP

Introduction

Documentation is an immutable record that serves as risk management for both patients and clinicians. There are several factors to consider in pursuit of excellent documentation. For example, examining chart entry and retrieval patterns provides clinicians with valuable information for self-critique. Utilizing objective tools also equip clinicians to capture and monitor patient progress more effectively. Another important consideration is careful and specific word choices and the phrasing used, which help convey clinical reasoning. To develop thoughtful solutions to common documentation conundrums, barriers to excellent documentation must first be identified.

elements elucidate Analyzing these how multidisciplinary tracheostomy teams can be part of the solution. While the SLP may take a lead role on a tracheostomy team, clear and comprehensive documentation in the medical record by all team members is critical to optimize patient safety and outcomes. Speech-language pathologists (SLP) hold a particularly unique position in managing and caring for people with tracheostomies due to their intimate understanding of the anatomy and physiology of the upper airway, which facilitates oral alimentation, respiration, phonation, and airway protection.

Mitigate Risk

The importance of comprehensive and clear documentation is primarily rooted in the fact that the hospital course of medical patients can be highly complex and dynamic, especially following a tracheostomy. The patients with tracheostomies are often critically ill, requiring frequent and protracted hospital stays, varied communication needs, and a team of specialists to effectively manage their care.

Silvestre et al. (2017) assert that when patients are transferred between various levels of care, there are many opportunities for insufficient communication of information, both verbal and written, which inevitably results in a "progressive and cumulative loss of information." The patient with a tracheostomy is particularly vulnerable to this type of miscommunication given median hospital lengths of stay (LOS) have been reported in some cases at 44 days (Bihari et al., 2018) and even 60 days (Cameron



et al., 2009). The extended LOS is often complicated by multiple transfers between the Intensive Care Unit (ICU), step-down or intermediate units, and medicalsurgical floors. Following hospital discharge, patients may be admitted to a rehabilitation center or longterm acute care facility prior to their final transition home or to another residential environment.

The "Swiss Cheese Model," as proposed by James Reason, is often referenced in the highly reliable organization (HRO) literature and provides a framework to consider how adverse events reach the patient. In this model, "the presence of holes in any one 'slice' does not normally cause a bad outcome. Usually, this can happen only when the holes in many layers momentarily line up to permit a trajectory of accident opportunity – bringing hazards into damaging contact with victims" (Reason, 2000) (see *Figure 1*). In this way, descriptive and non-ambiguous word selection and documentation is one of the best safeguards to prevent medical errors, near misses, and sentinel events from reaching the patients with tracheostomies.

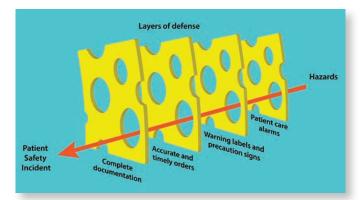


Fig. 1. Swiss Cheese Model

In addition to protecting the patient, thorough documentation serves as a means of risk management and liability prevention for the healthcare professionals. Gutheil (2004) details three essential principles for medical record documentation that mitigate accusations of negligence, including risk-benefit analysis, use of clinical judgement, and the patient's capacity to participate in their own care. Key documentation points related to the speech-language pathologist's scope of practice for the patient with a tracheostomy include areas that may impact overall care, such as type of services provided, clinical decisions and management, and the patient's level of function (see details in Figure 2).

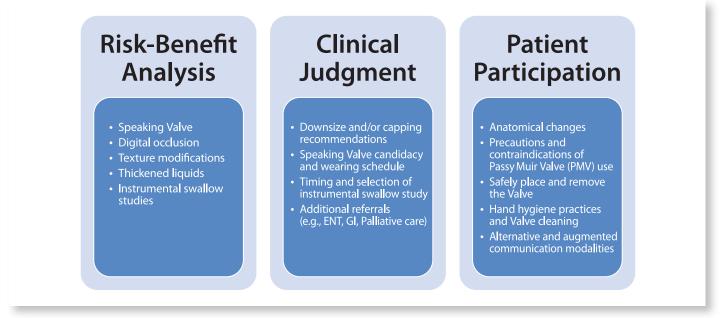


Fig. 2. Key Documentation Points

Weigh and Record the Risks and Benefits

Although the complexity and acuity of patients with tracheostomies can warrant a conservative approach, it is prudent to give equitable attention to both the risks and benefits of a prospective intervention in the medical record so that the team is aware of the considerations. In practice, there may be a tendency to be risk-averse, giving more weight to potential risks than to benefits. The Dual Process Theory is a framework that characterizes processing and decision-making as System 1 and System 2 thinking (see Figure 3). System 1 thinking relies on intuition, learned patterns, or comfort. By contrast, System 2 thinking is characterized as deliberate, strategic, and considerate of all available information. Since humans tend to prefer System 1 in order to conserve cognitive resources (Croskerry, 2009), it is conceivable that risks of a prospective intervention may be overemphasized in our clinical decisionmaking and documentation, which may manifest into the "not on my watch" or "this is the way it's always been done" mentality. Written risk-benefit analysis in our documentation may help steer toward System 2 thinking, and thereby give appropriate weight to both the risks and benefits.

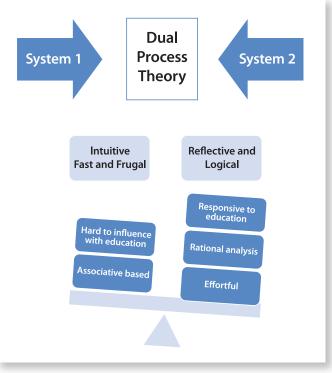


Fig. 3. Key Features of the Dual Process Theory

Convey Clinical Judgment

In terms of clinical judgment, Gutheil (2004) explains the concept of "primacy of the on-site observer," where in a malpractice case, the expert witness must determine whether the standard of care was met. The general practice is that the benefit of the doubt is given to the individual who was present during the event, as they were witness to details to which others are not privy. However, the benefit of the doubt is abdicated if clinical judgement is not documented (Gutheil, 2004). This is of particular importance with the patient with a tracheostomy, given the high incidence of aspiration.

According to the findings in a study by Donzelli et al. (2006), 47.5% of participants with a tracheostomy aspirated, and of those who aspirated, 78.9% did so silently, without any overt clinical signs. In another study by Leder (2002), 33% of patients aspirated, 82% of which were silent. And finally, a study by Elpern et al. (1994) revealed that 50% of individuals with a tracheostomy aspirated and 77% silently aspirated without clinical manifestation of airway invasion. These rates of aspiration occurrence are clinically significant. Tanner (2006) states "neglecting to conduct an instrumental evaluation of the swallow in cases of suspected dysphagia is analogous to refusing to X-ray a leg for suspected fractures." If the clinician were to forgo instrumental swallow studies in the tracheostomy population, it would require a record of sound clinical judgement and detailed documentation as to why the standard of care was not upheld. Indeed, the "clinical notes and reports become the primary evidence of your professional conduct and show your culpability, if any, in the negative dysphagia management outcome" (Tanner, 2006). Appropriate documentation of clinical judgement with sound reasoning is paramount.

Prioritize Patient-Centered Care

The final component identified by Gutheil (2004) is the ability of the patient and the patient's care partners to participate in their own care. Ethically, a patient has a right to autonomy, and legally, the patient has rights related to medical decisions and care. Patient engagement is critical for any patient with an artificial airway, as there are significant alterations in anatomy and physiology of the speech, swallow, and cough mechanisms following a tracheostomy that impact their ability to participate. There are additional risks and nuances related to infection control, rescue breathing, and secretion management. As such, not only must education be provided, but it is strongly suggested that the modality of education *Ethically, a patient has a right to autonomy, and legally, the patient has rights related to medical decisions and care.*

and training be provided (e.g., verbal, written, or demonstration). Additionally, there should be a thorough record of how the patient and care partners demonstrated understanding of the information, as this has serious implications regarding the efficacy of treatments, discharge planning, and overall trajectory of care. Another consideration is that patients with tracheostomies have a "loss of voice," so providing access to communication is essential. This may involve augmentative and alternative communication (AAC) forms, such as communication boards, or providing a speaking valve for voicing, such as the Passy Muir® Tracheostomy & Ventilator Swallowing and Speaking Valve. Access to communication is key for autonomy and participation in education.

Documentation Patterns

In a systematic review, Colicchio and Cimino (2019) detail findings related to four themes in medical documentation which include the note's purpose, clinician's reasoning, note entry, and note retrieval or reading strategies. The general purpose of documentation is obvious: patient care, billing and compliance, legal interests, research, and education. However, there are other relevant findings that should be considered. First, the authors identified that the thought processes or cognitive pathways a clinician uses to formulate an assessment and plan are based on the presence or absence of time constraints. Second, the authors found there is great variability in the use of templates and that the structure of the electronic medical record (EMR) affects what information clinicians decide to record (Colicchio & Comino, 2019). The assessment and plan section is often the first and most commonly read section, accounting for 67% of reading time dedicated just to this area, while the other sections are skimmed or possibly ignored altogether. And finally, discharge summaries frequently omit information pertinent to follow-up care.

While these findings may not seem particularly groundbreaking to many frontline clinicians, acknowledging these behaviors and patterns should prompt clinicians to closely examine their documentation practices. It is suggested that all members of a team use the same template and formatting for tracheostomy documentation. The entire multidisciplinary team benefits from uniformity, when possible. Moreover, the Assessment and Plan sections should be readily identified in the medical record in terms of display, format, and organization. These sections should be easily understood, avoiding unfamiliar and highly specialized jargon, and must contain the gestalt of the session. Finally, critical recommendations for follow-up care must be well-documented (e.g., speaking Valve wear schedule, recommendations for swallow diagnostics, consideration of tracheostomy tube change or downsize), which requires both written and verbal communication with physicians, case managers, direct care nurse, and others.

Put It into Practice: Word Selection and Phrasing

Pannbacker (1975) provided a succinct overview for how documentation should be organized with easy retrieval of specific information while avoiding ambiguous terms and overstatements. A few examples of how vague, non-specific wording can be replaced with highly descriptive and meaningful language to convey the patient's clinical presentation and the clinician's reasoning are presented in Table 1.

Weak Documentation	Increased Meaningful Documentation
Continue plan of care.	Will coordinate the next session with nursing to ensure the patient is up to chair in order to optimize positioning for speaking valve trial.
Hoarse/weak voice.	Patient was dysphonic with Passy Muir Valve in place, characterized using the GRBAS as Grade 2; Roughness 2; Breathiness 1; Asthenia 2; Strain 0, as judged during sustained phonation.
Patient did not tolerate PMV.	Patient demonstrated poor physiologic tolerance of the Passy Muir Valve, evidenced by audible and palpable back pressure upon removal of the Valve after 2 mins followed by intractable coughing lasting ~5 minutes.
Patient making no attempts to speak with PMV.	Despite no attempts to verbalize, the clinical benefits of the Passy Muir Valve for this patient may include restoration of subglottic pressure important for swallow function and cough strength, improved secretion management, core strength and trunk control, and decreased risk of atelectasis.

 Table 1. Documentation Examples

Put It Into Practice: Adjuncts to Current Documentation

Routinely, the notes will include the tracheostomy brand, tube size, and cuff status; secretions' quantity, color, and viscosity; and the patient's oxygen requirements and delivery mode. This information is critically important as it conveys information about the patient's status and helps guide treatment, including determining candidacy for speaking valve use. However, it is suggested that adding the supplemental details (outlined below) to the medical record will provide a more holistic view to ensure adherence to best practices and continuity of care.

- Interdisciplinary communication: Who was the plan discussed with? Did the discussion occur prior to or following the session?
- Precautions and warnings: What signage was posted and where? Were orders placed?
- Airway status: How was the patient found on arrival and left at the end of the session?
- Technology inventory and operational competence: Does the patient have access to a tablet or smartphone at bedside? If so, how well do they navigate it? Can the accessibility settings be modified to optimize non-verbal communication?
- Troubleshooting efforts: Was tracheal suction performed? Was the pilot balloon manually checked to ensure full cuff deflation? What modifications were made to the ventilator settings?
- Communicative bids: Was the patient mouthing words or gesturing? Or making eye contact or orally defensive behaviors?

Put It into Practice: Avoid Subjectivity

A common pitfall for the speech-language pathologist is serial assessment without use of high fidelity or highly sensitive tools. The objective should be to record measurable data about the patient's status for day-to-day comparison to better guide treatment and determine prognosis. A prime example can be taken from our wound care colleagues who use multiple methods of objective measurement (e.g., rulers, tracings) as well as highly descriptive terminology and commonly used nomenclature in order to minimize inter-observer subjectivity for an injury or illness that, much like a tracheostomy, requires close monitoring. Tools the speech-language pathologist may consider using for easily interpretable data collection that captures changes in presentation from session to session, facilitates inter-clinician care, and may be understood by all team members are provided in Table 2.

Table 2.	Informal	and	Formal	Assessment	Tools
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VOICE	GRBAS ¹ *	S/Z ratio ^{2,3}	Maximum Phonation Time (MT) ⁴
SWALLOW	Repeated Saliva Swallow Test (RSST)⁵	Peak Expiratory Flow Rate ^{6,7}	Oral Health Assessment Tool (OHAT) ⁸
COMMUNICATION	Words per breath group or speaking rate	Visual Analog Scale (VAS)** for Overall Communication Effectiveness	Tikofsky's 50-word Intelligibility Test

* GRBAS - Grade, roughness, breathiness, asthenia, strain scale

** Indicates clinician, patient, or care partner's rating.

¹ Hirano (1998) ² Van der Meer et al. (2009) ³ Eckel & Boone (1981) ⁴ Maslan et al. (2011) ⁵ Persson et al. (2018) ⁶ Bianchi et al. (2018) ⁷ Silvermani et al. (2014) ⁸ Chalmers et al. (2014)

This table does not provide an exhaustive list nor are the tools appropriate for all patient populations. Clinicians must be judicious and strategic in their selection of tools based on the patient's medical-surgical history, identified risk factors, level of consciousness, clinical presentation, and patient's goals of care and priorities. Importantly, none of the mentioned tools are sufficient in isolation nor are they meant to replace instrumental assessments of swallow function or direct visualization of the larynx and upper airway. The intent of these tools is not necessarily to determine if the patient's performance is within normal range, but rather to track progress and gauge response to rehabilitative and medical interventions. It should be emphasized that the tools are only as useful as the clinician's skill and understanding for how to use them and the description of how they were implemented. In other words, clinicians must be responsible for selecting the right tool, for the right patient, at the right time.

Identify and Understand the Barriers

Across clinical settings, there are a variety of formidable barriers and competing interests to implementing the practices described above. First, there are highly variable practice patterns and opinions on clinical documentation, even among clinicians on the same team at the same facility. For example, some facilities subscribe to the notion of "charting by exception," in which only unusual or unexpected findings are recorded. A clinician who is charting by exception would not document SpO₂ (oxygen saturations) if the patient has an oxygen saturation of 96%, given that this value is within the normal range. Conversely, other clinicians adhere to the idea that "what is not written does not exist." Understandably, such divergent approaches would lead to inconsistencies, redundancy, and likely frustration among the healthcare team.

Another common obstacle to comprehensive documentation may be attributed to employer productivity requirements, which vary depending on setting, population, and facility. Productivity is defined by the number of hours in direct patient care divided by the number of hours worked. According to ASHA's 2019 Health Care Survey, the mean productivity requirement among speech-language pathologists was 79.0% (American Speech-Language Hearing Association, 2019). Given the range of other necessary functions critical to providing quality patient care and safety, such as nursing and provider communication, administrative duties, education, and training, one can understand how comprehensive documentation may seem burdensome.

The ever-growing popularity of the multidisciplinary tracheostomy team is a step in the right direction in terms of addressing some of these challenges.

Finally, minimal charting requirements that are seemingly unrelated or at least not critical to the plan of care and scope of practice further add to the documentation demand. For example, home health clinicians may be required to capture and document the patient's vital signs; in acute care, clinicians often chart pain, fall risk, or acknowledge the nursing plan of care; and outpatient clinicians may be tasked with administering and documenting mental health screenings, reviewing medications, and other regulatory and facility-based requirements. Cumulatively, this may result in clinicians feeling pressured to document complex assessment and interventions as briefly as possible. This is reflective of the "know-do gap" concept, which is simply defined in the Implementation Science literature as the gap between what we know and what we do in clinical practice. Implementation science aims to "promote the systematic uptake of research findings and other evidence-based practices into routine practice" (Eccles & Mittman, 2006).

The Value of Collaboration

The ever-growing popularity of the multidisciplinary tracheostomy team is a step in the right direction in terms of addressing some of these challenges. The myriad of benefits provided by tracheostomy teams is well documented. These benefits include decreased length of hospital stay (LeBlanc et al., 2010), faster time to decannulation, and fewer adverse events (Cetto et al., 2011), thereby reducing overall hospital costs; while simultaneously increasing speaking Valve use (LeBlanc et al., 2010) and improving quality of life (Freeman-Sanderson et al., 2018). Teams give stakeholders the opportunity to engage in collaborative conversations about which critical components should be documented. The goal is not total standardization of clinical practice, as clinicians' autonomy and clinical judgement should be honored and upheld. However, it is a reasonable goal to minimize the range of subjectivity in documentation for the tracheostomy population. Once the key components of documentation are established among stakeholders, templates should be developed that are modified for efficiency to easily extract data from day-to-day entries. This requires a commitment to collaboration among healthcare team members, administrators, and information technology departments, in order to implement documentation optimizations while maintaining compliance parameters.

Conclusion

Documentation is a record of the healthcare providers' actions and their clinical decision making that serves not only the patient – but the interdisciplinary team. Comprehensive documentation should demystify clinical practice for other providers, in turn promoting a deeper understanding of how the service improves patient outcomes. It is risky to place the responsibility on the reader to extrapolate the rationale from reports, as this practice is rife with opportunities for misinterpretation, delays in care, overgeneralization, and, in the worst-case scenario, negligence. Applying evidence-based guidelines about documentation, chart navigation, and retrieval patterns, in combination with utilizing the schema of the Dual Process Theory and objectifying perceptual information should be documentation best practice. Standardization of documentation for the patients with tracheostomies will facilitate inter- and intra-patient comparison across sessions and clinicians. Establishing consistent nomenclature, procedures, and interventions, and incorporating reliable and valid measures, when possible, will bolster patient-centered care and improve patient outcomes (Martin-Harris et al., 2021).

Until multidisciplinary teams have a more ubiquitous presence, clinicians are encouraged to be action-oriented and take inventory of current documentation standards for their patients with tracheostomies at their facilities, collaborate and discuss among their team, and inform leadership and policymakers of pertinent findings. Clinicians are also urged to pay close attention to any unintended, yet positive, outcomes that may result. It is hypothesized that these may include improvements in capturing workload, coding and billing accuracy, data collection for quality improvement projects and funding sources, reimbursement, advocating for staff, and identification of knowledge gaps and training opportunities.

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Impact of an Interdisciplinary Tracheostomy Team on Patient Care at one Tertiary Trauma Center

Buffy Buchanan, MS, CCC-SLP | David Shane Harper, PA-C, MPAS, DFAAPA

Introduction

Since 1924, Northwest Texas Hospital in Amarillo, Texas has been the hub of medical innovation within the panhandle of Texas. While maintaining a tertiary trauma designation and providing services for the top twenty-six counties of Texas, eastern New Mexico and the panhandle of Oklahoma, Northwest Texas Hospital (NWTH) treats a variety of surgical and medical conditions. Utilizing its four hundred and ninety-five beds, many patients have been treated at NWTH over the years.

Due to a multitude of pathologic processes, such as traumatic brain injuries, cerebral vascular accidents, respiratory failure, and trauma, tracheostomy placements have been a common procedure for several surgical and medical specialty groups at NWTH. Compound this by tracheostomies being performed on patients of all ages, the standardization of care was seen as an opportunity to streamline the postoperative therapies and treatment. One aspect of post tracheostomy care that was felt to be underutilized was the Passy Muir® Valve (PMV®). Due to the patient population receiving tracheostomies having a multitude of diagnoses and no consistent standard of care, the application of the Passy Muir Valve was simply over-looked early on in their course. Communication and collaboration among caregivers are often impeded in the acute setting due to the high demands and workplace distractions. Furthermore, the lack of knowledge about tracheostomies may impact patient safety and well-being. Compounding these factors can be lengthy inpatient stays due to difficult disposition plans or financial constraints. For these reasons, the creation of an interdisciplinary tracheostomy team was seen to standardize and optimize the care for post tracheostomy patients.

Establishment and Impact of an Interdisciplinary Team Approach

A physician-led interdisciplinary tracheostomy team was developed to improve patient care by promoting safety, decreasing complication rates, and decreasing intensive care and total hospital length of stays (LOS) (see *Figure 1*). The multidisciplinary tracheostomy team included a surgical intensivist, a critical care physician assistant, speech-language pathologists (SLP), respiratory therapists (RT), physical and occupational therapists (PT and OT), nurses, nurse

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educators, social workers, and case managers. Subsequently, a protocol of postoperative orders was established and implemented for all post tracheostomy patients. This protocol provided for order sets for earlier intervention by therapies.

Since implementation of the interdisciplinary tracheostomy team in the acute care setting, we have observed a decrease in the intensive care unit (ICU) length of stay and overall length of stay by 50% (see Figure 1). Speech-language pathology is now assessing patients with tracheostomies much earlier for Passy Muir Valve trials, restoring communication sooner. SLPs are also conducting bedside swallow and instrumental evaluations earlier, resulting in an increase in oral feeding progression rates by 83% (see Figure 2). One-half of our patients in acute care are decannulated prior to discharge. Of our patients with tracheostomies, 50% discharge home while the others discharge to various levels of care (see Figure 3). Considering the patients who discharge to rehabilitation facilities, 65% are later decannulated prior to discharge from rehabilitation. These efforts also have provided a sizable financial benefit for the facility. Calculating intensive care unit length of stay before and after the implementation of the program revealed a savings of \$9.5 million dollars.

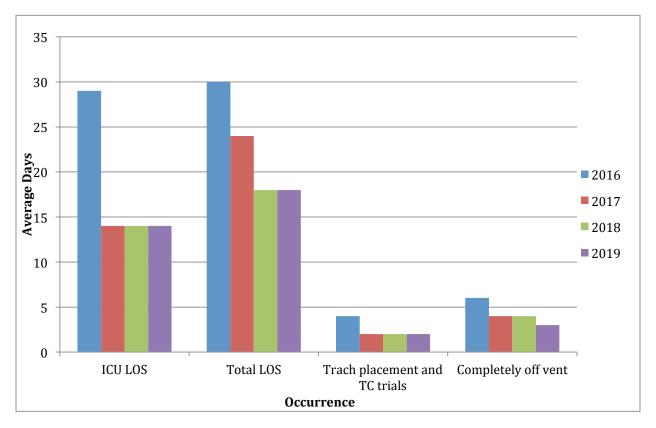


Figure 1. Pre-Implementation (2016) and Post-Implementation (2017-2019) of an Interdisciplinary Tracheostomy Team

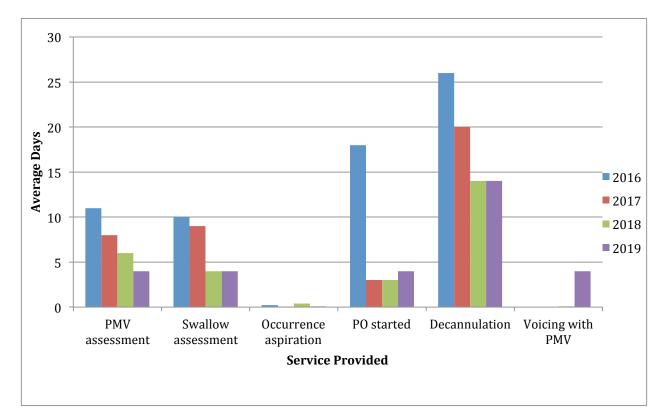


Figure 2. Pre-Implementation (2016) and Post-Implementation (2017-2019) of an Interdisciplinary Tracheostomy Team: Average Days to Service

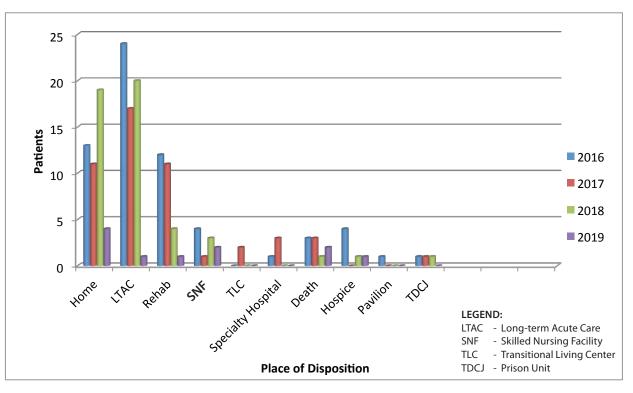


Figure 3. Place of Disposition Following Acute Care

Use of Fenestrated Tracheostomy Tubes

For years, there has been much debate over the use of non-fenestrated versus fenestrated tracheostomy tubes. Fenestration is not required for PMV use, but we have seen ease in breathing and improved loudness and phonation in cases with a fenestrated tracheostomy tube in place, especially for early intervention in the ICU. Risks of granuloma formation at the site of fenestration, high risk for aspiration of secretions, and difficulty ventilating patients are all concerns to be addressed with the use of fenestrated tracheostomy tubes. Through data collection with the interdisciplinary tracheostomy team at NWTH, we have assessed the:

- 1. Feasibility for using fenestrated tracheostomy tubes at initial placement versus non-fenestrated tracheostomy tubes in acute setting.
- 2. Positive versus negative outcomes for these patients with expected short term tracheostomy placements.

Our team has seen that when a fenestrated tracheostomy tube is initially placed, regardless of size 8 versus size 6, the speech-language pathologist is performing the PMV assessment within one day of the tracheostomy, and those patients are achieving voice on the same day of initial trial. Patients with non-fenestration receive Passy Muir Valve assessment on day four, due to poor airway patency closer to the time of the tracheostomy. Those with XLT (extended-length tracheostomy) tracheostomy tubes are assessed at day seven due to a combination of swelling from surgery and the extra length of the tracheostomy. The non-fenestration and XLT tracheostomy tubes appear to compromise airway patency more than the fenestrated tracheostomy tubes during the early stages post tracheostomy. In general, though, the non-fenestrated and XLT tracheostomy patients achieved voicing within one day of Passy Muir Valve assessments. Some of the patients with non-fenestrated and XLT tracheostomy tubes required a tracheostomy change or downsize for increased voicing and ease with Passy Muir Valve use. Speech-language pathologists at NWTH are assessing patients with fenestrated tracheostomy tubes with bedside swallow evaluations on the same day as initial Passy Muir Valve assessments. Patients with nonfenestrated or XLT tracheostomy tubes required an extra day for assessment, generally due to poor tolerance of the Passy Muir Valve or compromised respiratory status. Our tracheostomy team has seen that acute care patients with fenestrated tracheostomy tubes are decannulated an average of 18 days sooner than those with XLT tracheostomies and eight days sooner than those with non-fenestrated tracheostomy tubes. No long-term effects on morbidity or mortality have been identified.

continued next page

Patient Case Scenarios

The following scenarios are examples of a typical patient's course status post tracheostomy tube placement.

Scenario #1 – A 22-year-old female was admitted January of 2019 for multiple traumatic injuries following a motor vehicle accident. Patient had a size #8 cuffed tracheostomy tube placed five days after admission. The patient required downsizing to a size #6 fenestrated tracheostomy tube for a Passy Muir Valve assessment seven days after tracheostomy as she did not have good airway patency and exhibited back pressure prior to downsizing. She achieved voicing on the same day as the PMV assessment. A swallow evaluation by the SLP was completed a couple of days later, with aspiration noted. The patient participated in speech therapy and subsequently began an oral diet four days later. The patient was decannulated seven days after the swallowing evaluation and 21 days after tracheostomy placement. This patient's ICU length of stay was 21 days, before she was then transferred to the surgical ward. She spent eight days on the ward, making her total hospital length of stay 29 days before being discharged home under the care of her family.

Scenario #2 – A 26-year-old female was admitted in late December of 2018 for multiple traumatic injuries following a motor vehicle accident. The patient had a size #6 fenestrated cuffed tracheostomy placed three days after admission. Speech-language pathology assessed the patient for Passy Muir Valve use four days after her tracheostomy. She was able to achieve voicing on the same day as the PMV assessment. The swallow evaluation by the SLP was completed on the same day as well. Due to significant cognitive deficits, an oral diet had been withheld; however, oral intake was initiated the day after the PMV assessment. The patient was decannulated two days after PMV assessment and seven days after tracheostomy placement. The patient's intensive care unit length of stay was a total of eight days, before she was transferred to the surgical ward. She remained on the surgical ward for continuing therapies for two more days, before being discharged home under the care of her family.

Scenario #3 – An 18-year-old male was admitted in July of 2018 for trauma following a motor vehicle accident. The patient had a size #6 fenestrated, cuffed tracheostomy tube a week after admission. A swallow evaluation by the SLP was completed on the day of surgery. The patient's swallow function was within functional limits, and he began a diet that same day. The SLP assessed the patient for a Passy Muir Valve the day after the tracheostomy. He was able to achieve voicing on the same day as the PMV assessment. Decannulation occurred thirteen days after tracheostomy placement. The patient's intensive care unit length of stay was 12 days and then he was subsequently transferred to a rehabilitation unit for ongoing therapies. He remained there for two days before being discharged home under the care of his family. His total hospital length of stay was 14 days.

In each of these scenarios the patient expressed much appreciation for their tracheostomy tube placements. Each noted the discomfort of the endotracheal tube and frustration in not being able to communicate verbally. Several families were hesitant to proceed with tracheostomy tube placement as they saw the procedure as a "step backwards." Post tracheostomy and following removal of the endotracheal tube and its holder, most were quick to accept the tracheostomy for its benefits. This appreciation exponentially increased once the Passy Muir Valve was placed, and they could talk to their loved ones. The tracheostomy team provided education to all new tracheostomy patients and their caregivers. Extensive education regarding the purpose, expectations, and possible complications are explained and provided in print (with pictures) to patients and families. We have found that providing this personal education and materials have decreased much of the anxiety and stress expressed by patients and families regarding tracheostomy tube placements. Anecdotally, this education has also decreased the number and severity of complications with newly placed tracheostomy tubes as patients and families are more adept at identifying and appreciating upcoming or evolving problems.

Other benefits of this tracheostomy team's efforts and its methodology have reached beyond just patient satisfaction. Clinical staff satisfaction, specifically nursing and respiratory therapy departments, have voiced their pleasure with the tracheostomy team's protocols and procedures. By standardizing postoperative practices, all clinicians are aware of the anticipated course of treatment and modalities utilized to achieve them. Also, with the initial placement of the fenestrated tracheostomy tube, there has been a positive financial benefit, as the amount spent on tracheostomy tubes per patient is less due to the decreased need for tracheostomy tube changes during downsizing, specifically for those patients with short-term tracheostomy use. Here at NWTH, we have also seen improved tolerance of capping trials with the use of fenestrated tracheostomy tubes.

Impact of an Interdisciplinary Tracheostomy Team | Buchannan | Harper

Summary

Early tracheostomy placement has proven to be beneficial in several aspects. One area is the utilization of fenestrated tracheostomy tubes in initial tracheostomy placement for patients who are expected to need a tracheostomy tube for a temporary timeframe. After liberation from mechanical ventilation, this method allows for earlier Passy Muir Valve placement and evaluation of swallowing function, both of which immediately increases a patient's quality of life. Our tracheostomy team has shown that this method also allows for not only shorter intensive care unit stays, decreased hospital stays, and decreased cost associated with tracheostomy, but it also increased patient and staff satisfaction. Conversely, fenestrated tracheostomy tubes are not for all patients, as occasionally the curvature and fenestrated opening(s) of the tube does not align properly with the anatomy of the patient. Careful patient selection is part of the process for successful use of fenestration. However, we have found that initial tracheostomy tube placement with a fenestrated tracheostomy tube appears to be beneficial and with no foreseeable effect on morbidity or mortality.

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Article Summary

Use of PMV an Essential Intervention with COVID-19

Stierli, S., Buss, I., Redecker, H., Baumberger, M., Blättler, E., Selb, M., Hinter, S., Ischer, B., & Schwegler, H. (2020). Insights from an interprofessional post-COVID-19 rehabilitation unit: A speech and language therapy and respiratory medicine perspective. Journal of rehabilitation medicine, 52(9), jrm00100. https://doi. org/10.2340/16501977-2735

The objective of this study was to highlight that the early application of ventilator-compatible speaking valves (Passy Muir[®] Valve) is an essential therapeutic and rehabilitative intervention for COVID-19 patients. The authors present a general overview of seventeen post-COVID patients who required a tracheostomy and mechanical ventilation. The course of treatment for these patients included the following interventions: collaboration within a COVID-19 designated ward, interprofessional teamwork, and use of ventilator-compatible speaking valves. The authors present a specific case report of a 62-year-old male with severe acute respiratory distress syndrome due to COVID-19. His medical course is described, which includes speech pathology intervention for communication and swallowing therapy and use of in-line speaking valves may mitigate the potentially negative consequences of prolonged intubation, long-term use of cuffed tracheostomy, and post-intensive care syndrome resulting from COVID-19. They summarize that beyond benefits of communication and swallowing, use of the ventilator compatible speaking valve improves ventilator weaning, taste and smell, overall well-being, and quality of life.



Tracheostomy Teams Facilitate Early Therapeutic Interventions

Carmin Bartow, MS, CCC-SLP, BCS-S

Multidisciplinary tracheostomy teams provide numerous benefits, including decreased length of stay, expedited weaning from mechanical ventilation, earlier decannulation, and fewer tracheotomy-related complications (Santos et al., 2018). Additionally, tracheostomy teams facilitate early referrals to healthcare professionals who provide therapeutic interventions, such as speech-language pathologists (SLP), physical therapists (PT), and occupational therapists (OT), among others. Earlier referrals may result in increased use of Passy Muir® Valves (PMV®), with faster return to mobility and oral intake (Ceron et al., 2020; Fröhlich et al., 2017; Mah et al., 2017; Speed & Harding, 2013).

A recent study by Ceron et al. (2020) investigated the impact of a Passy Muir Valve on early intervention for mobility and physical function in ICU patients. They found immediate improvement when measuring functional mobility, as measured by the Perme Intensive Care Unit Mobility Score, for patients with tracheostomies and mechanical ventilation when comparing mobility prior to Valve use to immediately following Valve placement. When considering what aspects of mobility were affected, the authors found that the transfer category, including sit to stand, static balancing, and transfers, was the primary area of improvement. The authors attributed this finding to improved recruitment of abdominal muscles and increased in intra-abdominal pressure due to engagement of the glottis with PMV use.

Fröhlich et al. (2017) examined the impact of a multidisciplinary tracheostomy team approach on implementation of the Passy Muir Valve with patients. Patients who received the PMV with a team approach did so earlier in their care and had restored voicing, communication, and improved swallowing. One of the parameters reviewed in their study was the timing from tracheostomy to oral intake, finding that patients returned to oral intake sooner with a multidisciplinary team approach and PMV use. The authors concluded that with use of the PMV, intensive care patients on mechanical ventilation communicate verbally and swallow better (Fröhlich et al., 2017).

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Welton et al. (2016) described the benefit of using a tracheostomy team protocol that provides standardized order sets as this potentially increases earlier SLP involvement. The authors stated that having automated referrals to speech-language pathology resulted in faster access to verbal communication and earlier swallowing assessments. This earlier intervention resulted in a higher incidence of earlier oral diets with appropriate levels to decrease aspiration risk. They summarized that with timely SLP services, patients ultimately had improved quality of patient care.

The impact of a tracheostomy team on oral diets has been investigated (Mah et al., 2017). The authors reported significant improvement in the timing of speech-language pathology consults and in the tolerance of oral diets for patients with tracheostomy tubes after the tracheostomy service was implemented. They concluded that a critical step was involving the speech-language pathologist early in the post tracheostomy period (Mah et al., 2017).

Early swallowing intervention was investigated to address the feasibility of dysphagia rehabilitation in patients with tracheostomy and mechanical ventilation (Rodrigues et al., 2015). Their early rehabilitation program included use of the Passy Muir Valve inline with mechanical ventilation while receiving both indirect and direct swallowing therapy. The authors concluded that early swallowing rehabilitation is feasible for patients on mechanical ventilation and may help to improve the swallowing function and lessen oropharyngeal dysphagia severity. A multidisciplinary tracheostomy team is increasingly recognized as vital for improving the quality of life and safety of care for the patient with a tracheostomy. Additionally, tracheostomy teams can result in more timely referrals to therapy services. This allows the clinicians to provide earlier intervention for mobility, communication, and swallowing interventions. Early intervention has been shown to provide earlier use of the Passy Muir Valve with subsequent improved mobility, faster return to oral intake, and earlier verbal communication, thus improving patient outcomes and quality of life.

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Article Summary

Role of the SLP in the ICU

McCrae, J., Montgomery, E., Garstand, Z., & Cleary, E. (2020) The role of speech and language therapists in the intensive care unit. *Journal of the Intensive Care Society*, 21(4), 344-348. https://doi.org/10.1177/1751143719875687

The aim of this paper was to clarify the diverse range of skills, abilities, and specialties of speech-language pathologists (SLPs) and support their involvement in the management of patients with tracheostomies and mechanical ventilation in intensive care. The role of the SLP in the intensive care unit (ICU) included facilitating communication to restore communication for consent, day-to-day communication, and psychosocial well-being. The authors acknowledged that assessment for communication should begin early in the ICU and may initially involve establishment of nonverbal communication before transitioning to early cuff deflation trials and evaluation with a one-way speaking valve to restore airflow, phonation, and verbal communication. In support of dysphagia intervention, this paper clarified that early screening, assessment, and treatment of swallow function in the ICU was a preventative approach, reducing complications and poorer outcomes. This paper also promoted the SLPs' use of the one-way speaking valve to improve swallowing and cough to increase airway safety. The authors claimed that SLPs have such specific knowledge, understanding, and training of the physiology with regards to tracheostomy that they make valuable contributions regarding use of the one-way speaking valve and tracheostomy weaning. This paper proposed that not only are SLPs integral in the rehabilitation of speech and swallowing in patients with tracheostomies and mechanical ventilation, but as part of a multidisciplinary team, they also support the process of weaning and improve the patients' sense of well-being.



Case Study: Helping a Patient Regain Muscle Strength while Weaning from Mechanical Ventilation with a Passy Muir[®] Valve

Rachel dela Rosa, MS, CCC-SLP | Hao Chen, RCP, RRT

Introduction

Specializing in ventilator weaning, pulmonary rehabilitation, and care of medically complex patients, Barlow Respiratory Hospital in Los Angeles, California, delivers on its mission to help patients breathe easier. As a long-term acute care (LTAC) hospital, Barlow is widely trusted for the specialized care offered to chronically, critically ill patients in the post-ICU setting.

Developing and publishing a protocol specifically for weaning patients from prolonged mechanical ventilation enhances the care of patients with tracheostomy and mechanical ventilation. The Therapist-Implemented Patient-Specific (TIPS®) weaning protocol (see Figure 1 at end of article), developed by Barlow pulmonologists and based on years of specialized practice, has been nationally recognized and widely adopted by other hospitals. Use of this protocol includes introducing use of the Passy Muir Valve (PMV®) during the weaning process as a standard of practice. The Barlow TIPS weaning protocol is used for prolonged mechanical ventilation weaning. Some patients, especially those with muscle weakness, also benefit from PMV use for weaning.

Case Study

History

The patient is a 64-year-old male who was admitted to UCLA in the summer of 2019 due to progressive weakness, presumed to be chronic inflammatory demyelinating polyneuropathy with Guillain-Barre syndrome (CIDP with GBS) and respiratory failure. To begin interventions for rehabilitation, assessment of the patient was initiated. Assessment included addressing how to implement the Passy Muir Valve for ventilator weaning with this patient who was demonstrating significant muscle weakness.

When this patient first arrived, he was a quadriplegic with slight shoulder movement. His condition was not suitable to use the Barlow TIPS weaning protocol. We conservatively used the Passy Muir Valve to assist weaning from the ventilator. For in-line use, we used the Passy Muir[®] Tracheostomy & Ventilator Swallowing and Speaking Valve (PMV[®]007 (Aqua Color[™]). Initially, when we did in-line PMV evaluation and trials, he had a hard time voicing and phonating.

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He also was only able to use the PMV 007 for brief periods, no longer than a few minutes at a time.

Ventilator Management and PMV Assessment

When this patient arrived, the physician-initiated vent settings were (see Figure 2):

- SIMV 12
- Tidal Volume 500cc
- FiO₂ .30
- Pressure Support 10 cmH₂O
- PEEP 6



PMV[®] 007 (Aqua Color™)



Fig. 2. Ventilator Graphics

At the same time, initial PMV evaluation began with the respiratory therapist (RT) and speech-language pathologist (SLP) at the bedside, working together. To initiate the PMV assessment, the following processes were used:

- Assessment of the patient's vitals.
- Establishing baseline parameters.
- Patient's response including comfort.

We asked the patient if he was comfortable and adjusted our interventions appropriately. This included positioning the patient in the bed or chair and ensuring proper position of the tracheostomy tube and patient's head alignment. Typically, before we have the patient phonate, we will have the patient do something easier, such as humming or throat clearing. Then, we have the patient take a deep breath and attempt phonation. Often with this patient population, we remind the patient to phonate during exhalation because upper airflow is a lot for them to start getting used to again. This may include working with the patient to recognize inspiratory breaths from the ventilator and exhalatory effort. Often, this involves working with the patient to coordinate respiration and speech.

In the beginning, for this patient, we put the ventilator in NIV AC/VC (non-invasive ventilation mode with assist control/volume control), due to the patient having significant muscle weakness. We repositioned him and checked his HR (heart rate) and SpO₂ (oxygen saturation) before we started the initial evaluation. Establishing the patient's baseline parameters allowed us to monitor for change during the evaluation and subsequent treatments.

Part of the planning involved preparing a Passy Muir Valve, syringe, and Yankauer to have at the bedside and ready for use. We reviewed the plan for the evaluation and discussed with the patient what to expect before we started.

The first step involved deflating the cuff. To decrease patient anxiety, we explained to the patient that he would feel a lot of air through his nose or mouth. It may cause coughing or bring up secretions, which would all be normal. We reassured the patient that if anything bothered him or if he felt uncomfortable, to let us know and we would address it.

After deflating the cuff, we attached a warning label to the pilot line. The warning label was used to let the therapists, nursing staff, and others know that the cuff must be completely deflated before placing the Valve on the patient. We rechecked patient's HR and SpO₂ before and after cuff deflation and again after PMV placement.

The patient remained on NIV AC/VC while the cuff was slowly deflated. In this mode, the volume remains constant while the pressure may fluctuate, as needed. We added VT (tidal volume) to compensate for the leak that occurred with cuff deflation. The patient reported that he still felt uncomfortable with the same flow rate and tidal volume. The waveforms on the ventilator indicated that the patient's breathing was asynchronous. We then changed his ventilator settings to AC/PC (assist control/pressure control), a setting that allows pressure control to be constant and volume to fluctuate, as needed.

The patient reported feeling more comfortable on NIV AC/PC, with a flexible tidal volume and flow rate. The patient received consistent tidal volume and inhaled through upper airway. Ventilator waveforms showed the patient had better synchrony with this mode.

Assuring Airway Patency

You could see, even with the cuff deflated, the patient's respiratory rate was the same as the ventilator set rate (see Figure 3). The patient's ventilator trigger level was already set to the most sensitive level, without auto cycle, allowing the patient to initiate breaths if he was able.



Fig. 3. Set rate as compared to patient respiratory rate.

Before we put the PMV in-line, we assessed upper airway patency. To look at airway patency, we had several options:

- 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 (Sudderth, 2016).
- 2. Having the patient blow on a tissue, or blow on your hand; however, currently, with COVID-19, we limit these options to blowing on a tissue.
- 3. Assessing voicing on exhalation, listening for exhalation though the upper airway using a stethoscope (Sudderth, 2016).

We wanted to see if there was a leak before we put the Valve in-line. These measurements would suggest that the tracheostomy tube is properly sized and would allow sufficient airflow around the tracheostomy and out the mouth and nose. It also would suggest that there is no significant obstruction above the tracheostomy tube. The PMV then would be placed into the ventilator circuit while mechanical ventilation continues. After we put the PMV in-line, we also checked the patient's upper airway patency and Valve use by looking at exhaled tidal volume (VTe) and minute ventilation (VE). When we look at the ventilator (in our facility, a Puritan Bennet 840), it showed "00" on both of VTe and VE. This reading indicated that no exhalatory airflow was returning to the ventilator; there was no return tidal volume. With all readings indicating a patent airway for this patient, the Valve could be used in-line.

However, if none of these measurement options demonstrated exhalatory airflow or patency, then the patient may have had an airway obstruction. Obstruction may lead to observed back pressure – a release of air at the tracheostomy hub when the Valve is removed. Indications of difficulty include the patient coughing excessively or having a hard time breathing or phonating. So, considering cough, voice, and breathing pattern provide good parameters to evaluate when assessing a patient.

Addressing Barriers to Weaning

This patient was unable to wean off the ventilator in the past, with the barrier being muscle weakness. If we wanted to succeed in weaning the patient, we had to help the patient increase muscle strength. The PMV is a tool that may assist with increasing respiratory muscle strength. Using a PMV restores the body's closed system and restores airflow to the upper airway. It not only restores airflow but improves swallowing and speaking functions and restores respiratory mechanics and other functions. It especially helps to restore diaphragm function by adjusting pressure function in the chest, and it can also improve body stability. Human survival depends on the stability of the internal environment.

The PMV weaning strategy for this patient was to use the PMV 007 and progress from a high level of ventilator support and gradually dropping to a lower level of ventilator support (see Table 1). The next step would be to transition from in-line use of the PMV to a trach mask with cool aerosol and PMV. We checked the patient's negative inspiratory force (NIF) daily and monitored EtCO₂ (exhaled carbon dioxide) frequently to evaluate for improvement in respiratory muscle function.

Table 1.

Criteria for PMV Use: Depending on patient condition, we follow 4-level criteria to determine appropriate use of PMV. With these criteria, we are better able to manage different levels of PMV use for patients.

Level One: SLP only

These patients usually have weak swallowing and speaking function and have limited tolerance for PMV use. They require speech therapy to help in training and coaching. Most are beginning users for PMV.

Level Two: Under Supervision

Status for patients who can tolerate PMV a little longer. They may still have some risk related to wearing PMV independently (i.e., level of alertness, intermittent confusion, paralysis of extremities, anxiety, need for partial or complete restraint, need of intermittent oral and/or trach suctioning).

Level Three: In-Line PMV Only

These patients are still ventilator dependent, need a high level of ventilator support, or have difficulty weaning from vent support

Level Four: As Tolerated

These patients are usually off the ventilator and alert and oriented. They can use the call light for help. Respiratory status is stable, and they can participate in rehabilitation activities. Most of these patients are eligible for trach capping trials and/or decannulation.

Addressing Muscle Strength

During PMV weaning, we rely on changes to different ventilator modes, adjusting tidal volume, pressure control or pressure support levels, and trigger sensitivity. We gradually increase the time the patient uses the PMV. At the same time, physical therapy (PT) encourages the patient to use MOTOmed Movement Therapy (motorized movement therapy device that can be used in a bed or a chair) for upper and lower extremities exercises. Those methods really help the patient improve inspiratory muscles and improve extremity muscle strength.

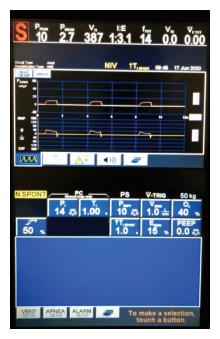


Fig. 4. Presssure support only.

Once the patient's NIF (negative inspiratory force) improved and PMV tolerance was longer, we changed the patient from NIV AC/PC settings to CPAP/PSV (continuous positive airway pressure/ pressure support ventilation), with pressure support only (see Figure 4).

The patient got stronger over time with therapy. He received therapy from PT, occupational therapy (OT), and the SLP. We taught him how to breathe consistently, managing his breath and speech coordination at the same time. We also worked on swallowing and eating. Activities of daily living and mobility tasks were all included in his therapies. When possible, we used the Passy Muir Valve during therapy as a tool to strengthen the upper airway to help with weaning from the ventilator.

The patient improved muscle strength. Whenever we see the patient's muscles becoming stronger, we also see an increase in tidal volume and titrate pressure support. When we dropped the pressure support to a certain level, maintaining the patient's tolerance, we were able to transfer the patient from CPAP to cool aerosol via trach mask. As the patient stayed on cool aerosol for longer periods of time, muscle strength became stronger. The patient's NIF progressed from "0" to "30" after one and half months of interventions.

"I have a voice now and it gives me options."

Patient's Perspective

The patient shared that the PassyMuir Valve was important to him. He stated, "I have a voice now and it gives me options. When I first arrived, it was incredibly difficult. Not all the staff are patient enough to try to understand, especially when you try to explain it to staff who cannot hear you. It is really, really hard. This has been a good adjustment. When you have a voice, you can tell the caregiver. This has been helpful, and the staff have been supportive and in moving me along. Thank you."

Vent Terms

A/C (Assist Control) – a mode of ventilation; machine does all the work; if the patient attempts to trigger a breath, the vent will deliver the preset volume/pressure setting at the preset rate.

CPAP (Continuous Positive Airway Pressure) – mode of ventilation that requires patient to initiate breaths (spontaneous breathing only); breaths per minute are determined by the patient.

NIV (Non-invasive ventilation) – mode of ventilation available on some ventilators; offers alarm options for longer term Passy-Muir Valve applications.

PS (Pressure Support) – mode of ventilation; used during spontaneous breathing; the ventilator delivers a pre-set pressure, with a variable volume.

V/C (Volume Control) – how the patient receives their breath from the ventilator; preset volume of air that remains constant.

VE (minute ventilation) – volume of inspiratory or expiratory air in one minute. (VE = Vt x f)

VTe (exhaled tidal volume) – amount of expiratory volume (air).

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Fig. 1. Barlow TIPS Weaning Protocol



At Barlow Respiratory Hospital, we provide the highest quality respiratory care. Our expert team of Barlow Physicians, Nurses and Therapists draw upon more than a century of respiratory health expertise. We are considered a leader in ventilator weaning, and specialize in serving patients with chronic critical illness and complex respiratory conditions who are dependent on a ventilator to take their next breath.

THERAPIST-IMPLEMENTED PATIENT-SPECIFIC (TIPS[©]) PROTOCOL 2.0 *

*Physician order for TIPS[®] Protocol triggers Speech Therapist evaluation for Passy-Muir Speaking Valve

DAILY WEANING EVALUATION (DWE)

Do NOT proceed to weaning trials if any of the following are present:

- Hemodynamic instability
- Vasopressor infusion used to stabilize blood pressure
- Systolic blood pressure < 90 mmHg
- Pulse < 50 or > 130 BPM or increase from baseline > 20
- Respiratory rate > 35 BPM
- O2 saturation < 90%
- Temp >100.4
- FiO2 > 0.5 or PEEP > 8
- Prominent accessory muscle use
- Spontaneous tidal volume <0.25 L

A: SBT TRIALS

- 1. SBT as tolerated return to original ventilator settings after 4 hour trial
- SBT as tolerated up to 8 hours, then return to prior ventilator settings 2.
- 3. SBT as tolerated up to 12 hours, then return to prior ventilator settings
- SBT as tolerated up to 16 hours, then return to prior ventilator settings
- 5. SBT as tolerated up to 20 hours, then return to prior ventilator settings
- 6. SBT as tolerated up to 24 hours

B: CPAP/PS TRIALS

- 1. AC to CPAP 5 w / PS 20 not to exceed 10-12 hours
- 2. CPAP w/ PEEP 5 / PS 18 not to exceed 10-12hours
- 3. CPAP w/ PEEP 5 / PS 16 not to exceed 10-12 hours
- 4. CPAP w/ PEEP 5 / PS 14 not to exceed 10-12 hours
- 5. CPAP w/ PEEP 5 / PS 12 not to exceed 10-12 hours
- 6. CPAP w/ PEEP 5 / PS 10 for 10-12 hours

Continue to A: SBT Trials

with result to MD)

C: SIMV/PS TRIALS

Reduction of ventilator support: up to 3 steps per day at Q3h intervals

Reduction of SIMV:

1. AC to SIMV 10 / PS 20	2. SIMV 8 / PS 20
3. SIMV 6 / PS 20	4. SIMV 4 / PS 20
Reduction of	of PSV:
5. SIMV 4 / PS 18	6. SIMV 4 / PS 16
7. SIMV 4 / PS 14	8. SIMV 4 / PS 12
9. SIMV 4 / PS 10	
Self Breathin	ng Trials:
10. 1 hour	11. 2 hours 🗲 (ABG)
12. 4 hours	13. 6 hours
14. 8 hours	15. 10 hours
16. 12 hours	17. 16 hours
	3. SIMV 6 / PS 20 <i>Reduction c</i> 5. SIMV 4 / PS 18 7. SIMV 4 / PS 14 9. SIMV 4 / PS 10 <i>Self Breathin</i> 10. 1 hour 12. 4 hours 14. 8 hours

- 19. 24 hours

LEGEND / GLOSSARY

18. 20 hours

AC – Assist Control CPAP – Continuous Positive Airway Pressure PEEP – Positive End Expiratory Pressure PS – Pressure Support SBT – Self Breathing Trials SIMV – Synchronized Intermittent Mandatory Ventilation Passy-Muir Speaking Valve - commonly used to help patients speak more normally, attaches to the outside opening of the tracheostomy tube. Ventilator Weaning - gradual withdrawal of mechanical breathing support through utilization of a variety of ventilator modes, periods of total spontaneous ventilation, and appropriate rest periods

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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.

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 noleak 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.



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 SPO₂ (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 strengthtraining these muscles transfers to the functions of cough and swallow (Pitts et al., 2009).

Table 1

Inspiratory Muscle Training (IMT)	Expiratory Muscle Training (EMT)
 Abductor Vocal Fold Paralysis¹ Ventileter weeping (Paralysis of Disphragm)² 	 Dysphagia³ Courde (aigway alegrapsa, aigway protection)⁴
 Ventilator weaning (Paresis/Paralysis of Diaphragm)² 	 Cough (airway clearance, airway protection)⁴ Voice/Breath Support for Speech⁵

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 ₂ O to 30 cmH ₂ O	IMT/EMT
EMST75 Lite	Pressure Threshold	$0 \text{ cmH}_2\text{O}$ to 75 cmH $_2\text{O}$	EMT
EMST150	Pressure Threshold	$30 \text{ cmH}_2\text{O}$ to $150 \text{ cmH}_2\text{O}$	EMT
Respironics Threshold PEP	Pressure Threshold	$0 \text{ cmH}_2\text{O}$ to $20 \text{ cmH}_2\text{O}$	EMT
Respironics Threshold IMT	Pressure Threshold	9 cmH ₂ O to 41 cmH ₂ O	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 H₂O, cough requires 100-200 cm H₂O, and having a bowel movement requires 200-300 cm H₂O (Sapienza, 2021). If a patient is not able to produce pressure within those ranges, then RMT may be an intervention to consider.

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, speechlanguage 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:
 - o Presence of dentures (and fit)
 - o 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



A Conscious Approach to Decannulation: Clinical Application of Passy Muir[®] Valves with Disorders of Consciousness

Marilouise E. Nichols, MS, CCC-SLP | Ashley Munoz Lopez, MS, CCC-SLP, BCS-S

Disorder of Consciousness (DoC) is a state of prolonged altered consciousness that is usually characterized by coma, unresponsive wakefulness syndrome, or minimally conscious state based on neurobehavioral function. The pathophysiology of DoC is not fully understood, but recent advances in neuroimaging and electrophysiological techniques have improved the understanding of the neural system responsible for consciousness. DoC rehabilitation programs promote arousal through stimulation while preventing secondary medical complications and providing education and training. Therapeutic interventions are diverse, but there is a lack of consensus regarding treatment guidelines for individuals with DoC (Eapen et al., 2017).

Coma

• state of deep unconsciousness that lasts for a prolonged or indefinite period

Unresponsive wakefulness syndrome (previously known as vegetative state) (UWS)

 lost awareness of self and external environment but have eye opening

Minimally conscious state

• severe but not complete impairment of awareness; often follows coma or UWS

As the breadth and depth of knowledge surrounding Disorders of Consciousness, a unique clinical subset of severe acquired brain injury (sABI), rapidly grows, an inevitable shift in clinical practice becomes necessary, particularly for DoC patients with tracheostomies. Approximately 100,000 tracheotomies are performed annually in the United States, and of those, an estimated 50-70% are within the sABI population (Yu, 2010; Richard et al., 2005). Consistent with today's medical care trend, the initial and ongoing costs of tracheostomy care is far from nominal, with patients with tracheostomies accruing some of the highest patient care costs (Engoren et al., 2004; Altman et al., 2015). Severe acquired brain injury comprises a significant fraction of the financial burden on the healthcare system, as well as costs to

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families, caregivers, and society; therefore, the primary goals of therapeutic intervention for this population should be to improve functional outcomes in an effort to reduce this financial burden and transition towards the most cost-efficient care (Maas et al., 2008). Particularly, safe and timely decannulation of patients with sABI, specifically for those within the DoC population, should be high priority from both patient care and financial standpoints. However, tracheostomy weaning and decannulation in the DoC population has historically been faced with challenges and failures, which is starkly contrasted to the more positive weaning and decannulation outcomes seen in general trauma patients and other patient populations with tracheostomies (Perin et al., 2017; Engoren & Arslanian-Engoren, 2005).

Argument for Use with the DoC Population

Given the medical and clinical complexity of the DoC population, formulating guidelines for decannulation may be difficult; therefore, it requires education and collaboration from a multidisciplinary team with expertise in brain injury. Having involvement from a multidisciplinary team provides the rehabilitative services necessary to produce the best outcomes for discharge to society and improved quality of life (Semlyen et al., 1998; Rubin et al., 2019). Rehabilitation services for DoC patients should be provided by a team comprised of, but not limited to, physicians, physical therapists, occupational therapists, speechlanguage pathologists, and nurses, whose efforts are focused on individualized cross-disciplinary treatment goals that enhance health, mobility, selfcare, communication, and participation (Giacino et al., 2020).

Despite the abundance of literature highlighting the benefits of the Passy Muir® Tracheostomy & Ventilator Swallowing and Speaking Valve use in patients with tracheostomies, presently, the literature sorely lacks explicit support of the use of a Passy Muir® Valve (PMV[®]) with patients with DoC. However, the foundations of neuroplasticity and the "use it or lose it" concept reinforce the need for early intervention with PMV application in the DoC population and may result in improved rehabilitation outcomes and management (Kleim & Jones, 2008). Current review of the literature provides evidence for use of a multidisciplinary team at neurointensive facilities and to consider implementation of PMV placement with patients in the DoC population. Implementation of PMV use with the DoC population was considered in an effort to increase wakefulness and awareness. progress towards decannulation, improve patient outcomes, and reduce medical costs.

The benefits of PMV application in the progression towards decannulation is well-documented and often drives the early introduction of PMV in patient care plans (Tobin & Santamaria, 2008; Santos et al., 2014; Medeiros et al., 2019). However, DoC patients may not demonstrate typically recognized signs of readiness for PMV, such as wakefulness, responsiveness to environmental stimuli, and/or making communication attempts. Frequently, they are not provided the opportunity for PMV placement, thus missing out on the clinical benefits associated with PMV application. Use of the PMV in-line with mechanical ventilation has been shown to improve lung recruitment and diaphragm involvement, resulting in improved mechanics of the respiratory system, and leading to expedited decannulation (Sutt et al., 2015; Sutt et al. 2017; Brooks et al., 2019). For patients on aerosolized trach collar, the use of PMV provides similar respiratory benefits that may lead to more rapid decannulation (Brooks et al., 2019). Perhaps the current ideas of PMV application readiness may inadvertently be excluding the DoC patient population from timely progression towards decannulation, in turn, negatively affecting patient care and patient quality of life, while increasing the financial burden on families and healthcare facilities.

Despite the substantial growth in knowledge and frequency of PMV application over the years, largely due to increased clinical research and clinician education, DoC patients are often overlooked for PMV application, as these bodies of research do not include DoC participants. For example, several studies only address speaking valve use with patients who are awake, responsive, and attempting to communicate, which, by definition, excludes DoC patients (Freeman-Sanderson et al., 2016; Sutt & Fraser, 2015; Sutt & Fraser, 2017). DoC patients, however, continue to be at equal risk of medical complications associated with long-term tracheostomy, such as infection, granulation tissue, stenosis, tracheomalacia, and increased morbidity (Enrichi et al., 2017; Lawet et al., 1993; Frederik et al., 2012), which further underscores the importance of early intervention with the PMV to facilitate timely decannulation within the DoC population.

DoC Rehabilitation Programs and Decannulation

The foundation of DoC rehabilitation programs is to increase awareness and wakefulness through sensory stimulation. When considering the principles of sensory reception and perception, PMV placement would be effective in helping to stimulate these sensory-based targets, utilizing environmental stimuli to engage areas of the brain that recognize smells, textures, and tastes (Halper et al., 1999). The presence of the tracheostomy tube can result in decreased sensation to the pharvnx and glottis. but the redirection of airflow with PMV placement provides sensory stimulation to the oropharynx and can improve management of secretions, as well as improve taste and smell (Eibling & Gross, 1996; Lichtman et al., 1995; O'Connor et al., 2018). Another consideration is that stimulation and engagement of specific brain functions, such as taste and smell, may also result in improved cognition (Kleim & Jones, 2008).

Standardized diagnostic measures, specifically used to assess patients in the DoC population, may also be administered in a more robust and comprehensive manner with use of the PMV. The primary indications for use of standardized measures in this population include diagnostic assessment, outcome prediction, projection of disposition needs, interdisciplinary treatment planning, and monitoring treatment effectiveness (Kalmar & Giacino, 2005). Of the available standardized assessments tailored for the DoC population, the Coma Recovery Scale-Revised (CRS-R) has emerged as the gold standard of DoC assessment. It is important to note, however, that scoring for the CRS-R assessment is based on the presence or absence of specific behavioral responses to sensory stimuli, such as taste and smell; therefore, patients with tracheostomies who do not use a PMV are not provided the opportunity to participate fully in the CRS-R assessment. However, with a PMV in place, their senses, such as taste and smell, would be restored and accessible during assessment.

Further, a patient's performance on the CRS-R assessment may provide objective data on the progression of patient's cognitive status. Level of cognition has been frequently used as clinical criterion for decannulation readiness (Wannez et al., 2017). Therefore, comprehensive use of the CRS-R assessment, including taste, smell, and communication subsets with a PMV in place, may be a critical part of the decannulation protocol within the DoC population. Mortensen et al. (2020) underscored the need for routine and repeated evaluation using CRS-R assessment as a part of the decannulation process.

It is recommended that DoC patients be supervised during Passy Muir Valve trials, with close attention to state, work of breathing, and vital signs. This can facilitate utilization of PMV across therapy disciplines during various treatment sessions to ensure frequency and magnitude of stimulation for swallow, cough production, and communication (Kleim & Jones, 2008; Brooks et al. 2019). Ceron et al. (2019) found that PMV placement is also effective in improving patient capacity for mobility, which is an integral component of the interdisciplinary DoC rehabilitation plan.

A strong and productive cough is consistently cited as one of the most important criteria for decannulation. Research by Perin et al. (2017) found that patients with a strong, productive, and spontaneous cough were more likely to have successful decannulation. It is important to note that DoC patients without the opportunity for PMV placement will be unable to demonstrate cough ability; however, with the Passy Muir Valve, improvements occur in sensation and subglottic pressure, assisting with a more functional cough response (Fernandez Carmona et al., 2015). Therefore, to improve successful decannulation rates among DoC patients, it is imperative that clinicians evaluate and utilize PMV application as a means for patients to demonstrate cough ability. This underscores how early evaluation and application of Passy-Muir Valve placement may result in timelier decannulation in the DoC population.

Parameters for Decannulation

Unfortunately, the parameters for decannulation in the DoC population are unclear. In fact, there are no specific guidelines for decannulation in patients with DoC (Hakiki et al., 2020; Ceriana et al., 2003; De Leyn et al., 2007; Bach & Saporito, 1996). Medical professionals often have difficulty agreeing on what constitutes an appropriate decannulation protocol for DoC patients, as well as reluctance to implement decannulation protocols (Hakiki et al., 2020). A study by Mah et al. (2016) supports the use of the PMV for patients with tracheostomies as a part of an ICU tracheostomy care bundle, as it has shown to positively correlate with decannulation and the initiation of oral feeding prior to discharge. Once these patients leave the ICU and transition to other units or facilities, however, implementing tracheostomy care bundles becomes more challenging. The patient's primary diagnosis and clinical complexity often overshadows the tracheostomy needs and progression towards decannulation. DoC patients are also noted to be transitioning to rehabilitative facilities sooner; therefore, the role and responsibility of progressing these patients towards decannulation is often transferred to the multidisciplinary team at the next level of care. By not implementing a plan for decannulation in the DoC patient population earlier, there is potential for adverse events and increased morbidity in this already high-risk and high-cost patient population.

Additional Benefits with Swallowing

In addition to sensory stimulation and cognition assisting towards decannulation, PMV placement also provides benefits in swallowing function for patients with tracheostomies and DoC. Due to the improved subglottic pressure, increased upper airway sensation, and restoration of a near-normal aerodigestive tract, swallowing treatment is best completed with a PMV in place. Patients with prolonged disordered consciousness are likely to have weakened glottic closure response, which is associated with aspiration, further underscoring the need for early swallowing intervention in DoC populations (Leder & Ross, 2005). Melotte et al. (2017) emphasized the importance of assessing swallowing function in patients within the DoC population, as those with "no evident sign of consciousness" have been observed to demonstrate some functional swallowing abilities. Best practice suggests that objective swallowing assessments, such as Modified Barium Swallow Studies (MBSS) or Fiberoptic Endoscopic Evaluations of Swallowing (FEES), be performed prior to initiation of oral intake,

and the current literature suggests that these evaluations may be performed safely in patients regardless of their level of consciousness (O'Neil-Pirozzi et al., 2003; Brady et al., 2006; Bremare et al., 2016).

PMV placement in conjunction with instrumental swallowing assessment are valuable tools in the DoC rehabilitation process and can advance patients towards safe and therapeutic oral feeding (Brady et al., 2006). Following instrumental swallowing assessment, dysphagia treatment may target using PO trials as sensory stimulation and serve to facilitate the patient's overall rehabilitation goals of neurobehavioral recovery (Brady et al., 2009). Aside from PO intake, FEES is an important and effective tool in assessing secretion management – a parameter that is often used when considering decannulation in patients with long term tracheostomies, such as within the DoC population, in the rehabilitation setting (Enrichi et al., 2017). The redirection of upper airflow and oropharyngeal stimulation that occurs as a result of PMV placement can improve secretion management (Lichtman et al., 1995; O'Connor et al., 2018).

Conclusion

Integrating early PMV application for the DoC population truly requires a deliberate effort from all members of the multidisciplinary team and possibly a shift from previous ideas about PMV application and decannulation. For patients with tracheostomies, one of the long-term goals should always be decannulation, as medically appropriate. Decannulation has benefits such as decreased medical complications, decreased infections at the tracheostomy site, decreased medical care costs, decreased caregiver burden, but most importantly, improved quality of life and functional outcomes for patients. However, patients in the DoC population are often tracheostomized longer than other trauma patients and are not considered candidates for decannulation, as there are no specific decannulation guidelines for this specific clinical population. The benefits of PMV application in progression towards decannulation are well-known and well-documented throughout the literature. If this knowledge is applied to the DoC population, the steps towards decannulation should begin in the acute phase of the medical course and include PMV placement. With PMV application, DoC patients have greater recognition of environmental stimuli, such as taste and smell; participate more in comprehensive and standardized DoC cognitive assessments, such as the CRS-R; are provided with opportunities to use verbal communication; have improved swallow function and secretion management; and may demonstrate improved cough ability - all of which have traditionally been clinical indicators for decannulation readiness. While the research regarding PMV placement in the DoC population is limited, the rationale and benefits of the PMV remain the same as with other populations with tracheostomies, and the goal of safe and timely decannulation is paramount.

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Aerodigestive Changes for Swallowing and Feeding in the Neonatal Intensive Care Unit (NICU)

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The prevalence of aerodigestive challenges leading to feeding and swallowing difficulties is high for sick term and preterm infants in the neonatal intensive care unit (NICU) (Shaker, 2017a; Jadcherla, 2016). Establishing full, safe oral feeding in the setting of complex co-morbidities requires a collaborative infant-guided approach (Shaker, 2017b). Problemsolving critical decisions about developmental expectations and cautious opportunities to feed are essential to optimizing feeding outcomes after the NICU (Ross & Browne, 2013). Some of the more common feeding-related challenges in the NICU are discussed below.

Q: What are your current practices regarding oral feeding for NICU infants who have been recently extubated?

A: I am part of the team in a large level IV NICU which serves sick newborns and the sickest and the most fragile preterms, some born at 22 weeks gestational age. Intubation and ventilation are avoided, when possible, with a goal of stabilization on non-invasive positive pressure ventilation (NIPPV) or continuous positive airway pressure (CPAP) in the delivery room.

NICU infants, when extubated, often require levels of respiratory support that continue to delay oral feeding. Once an infant is stable on NIPPV, the neonatal therapist can support feeding readiness for infants with complex co-morbidities, including prolonged intubation and/or sequelae, especially respiratory; and/or neuro; gastrointestinal (GI); airway; cardiac; and/or neuromotor processes (Jadcherla et al., 2009).

Unfortunately, well-intentioned oral feedings for which the infant is not ready may wire the brain away from eating, lead to later feeding aversions, and adversely affect the already fragile infant-parent relationship (Shaker, 2013c). The literature on feeding outcomes in former preterms includes a high percentage of former preemies with enduring feeding problems, far beyond their NICU stay (Ross & Browne, 2013). Care must be taken to match readiness with opportunities to progress to oral feeding.

Even sick newborns who require intubation and ventilation are fragile, once extubated, and may have sequelae that adversely affect oral feeding. Fragile preterms, had they not been born early, would have experienced motor learning and oral-motor learning in utero. Their oral-motor patterns would have evolved

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in the context of the containment provided by the uterus, with their hands on the face and in the mouth while alternating with touching the placenta. During all infant-guided feeding readiness experiences, careful attention and watchful vigilance are required for signs of physiologic stability or instability, especially the impact on work of breathing and respiratory rate (Shaker 2017a). Progression from sucking on their own hands to pacifier sucking, offered via rooting response with co-regulated pacing, is followed by tiny droplets of expressed breastmilk on a pacifier offered for purposeful swallows – building nonnutritive suck-swallow-breathe synchrony on the infant's own timeline of skill progression.

In the NICU, every experience matters, especially every feeding experience. Well-planned therapeutic experiences will best support underpinnings for eventual opportunities for coordinated feeding and airway protection.



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Q: How safe is feeding on HFNC (High Flow Nasal Cannulae) or CPAP (Continuous Positive Airway Pressure)? There is pressure to feed infants and get them home. How do we minimize risk and navigate dialogue with physicians?

A: Unfortunately, often the conclusion regarding the "safety" and the "tolerance" of NICU infants feeding on CPAP is determined by volume and perhaps lack of overt or symptomatic decompensation. Recent studies were done on the effect of CPAP under videofluoroscopy (Dumpa et al., 2020; Ferrara et al., 2017). In one study, their preliminary findings regarding aspiration were so worrisome that the neonatologists stopped the research project. The study determined that "oral feeding while on CPAP significantly increases the risk of laryngeal penetration and tracheal aspiration events," and recommended caution when initiating oral feedings on CPAP. Unfortunately, the conclusions did not focus on changes in swallowing physiology under CPAP, which would have been instructive. It is not only aspiration that is worrisome; altered swallowing physiology increases risk for airway invasion. It is not uncommon for neonates to evidence changes in swallowing physiology due to respiratory comorbidities, even when stable on less respiratory support or indeed on unassisted room air.

NICU technology has advanced such that infants as early as 22 weeks gestation are surviving.

Many of our former preterms do indeed learn to feed orally when respiratory co-morbidities better permit, such as once weaned from HFNC, and, in my experience, do so more safely with much less physiologic stress.

NICU technology has advanced such that infants as early as 22 weeks gestation are surviving, and many infants born extremely premature may require extended periods of CPAP and HFNC. Those infants with the greatest respiratory co-morbidities, often those born < 28 weeks gestation and BW < 1000 grams (Jadcherla et al., 2009), are most likely to require CPAP and/or HFNC at those post-menstrual ages when oral feeding is often attempted. Sick newborns may also present similar issues, secondary to their comorbidities. If a neonate has such respiratory needs that CPAP or HFNC is required, one must ask if oral feeding is really a priority at that time. The neonate's ability to safely reconfigure the pharynx from a respiratory tract and back to an alimentary tract with precise timing and coordination surrounding each swallow is already fragile. Under these conditions, it is worrisome. When we look objectively in radiology during an instrumental assessment of swallowing physiology, our data suggest that even neonates with respiratory co-morbidities who are stable on unassisted room air often have altered or impaired swallowing physiology. The bolus misdirection and resulting aspiration we often observe is, unfortunately, typically silent.

A neonate with increased work of breathing and "air hunger" may have the need for an "urgent breath." This may then predispose the infant to difficulty maintaining glottic closure throughout the duration of the swallow. This uncoupling of swallowing and breathing may lead to airway invasion (Ferguson et al., 2015).

We cannot conclude that feeding under these conditions is "safe," without objective data on the impact of CPAP or HFNC on an infant's swallowing physiology. If your NICU's protocol includes feeding infants on CPAP or HFNC, safety may be optimized by one to two very brief, cautious oral feeding experiences with the neonatal therapist for interval motor learning. Infant-guided interventions (swaddled elongated side-lying, slow flow nipple, strict coregulated pacing, and resting) should be used, with watchful vigilance (Shaker, 2017b). Then, this would be followed by an instrumental assessment of swallowing physiology in radiology to objectify the impact of HFNC or CPAP on airway protection and swallowing physiology.

Even if there is no witnessed aspiration during a dynamic swallow study, the infant may aspirate during a true feeding; the swallow study is a moment in time (Ferguson et al., 2015). Our focus during a swallow study needs to be on physiology because altered physiology and its etiologies may create conditions during a true feeding under which bolus misdirection may or does occur. These "conditions" may include intermittent changes in position, sucking rate and length, variations in timeliness and depth of breathing, and caregiver's feeding approach. Analysis of radiologic data would occur in the setting of that infant's unique history and co-morbidities. From there, we would dialogue with the team to support safety and neuroprotection (Shaker, 2017a).

Neonatal terminology:

Full-term – 40-weeks gestational period (pregnancy)

Preterm – birth occurring before the 37th week of pregnancy

Sick term - full-term but requiring neonatal intensive care due to illness and/or co-morbidities

Chronological age (CA) – the number of weeks since birth

Gestational age (GA) – the number of completed weeks elapsed between the first day of the last menstrual period and the date of birth; *weeks in the intrauterine space since birth*

Postmenstrual age (PMA) – gestational age plus chronological age; weeks in the intrauterine space plus weeks since birth

Increased work of breathing – excessive breathing effort; may include nasal flaring/blanching, chin tugging, suprasternal and/or supraclavicular retractions; often co-occurs with tachypnea (a rapid respiratory rate).

Interventions:

Resting – providing infant-guided breaks/brief rest periods

Slow flow nipple – nipple that provides a reduced, controllable rate of flow to enhance suck-swallowbreathe coordination

Co-regulated pacing – imposed pauses from sucking based on the infant's physiologic and behavioral communication to the caregiver. Goal is to maintain physiologic stability rather than respond to distress.

Swaddled – infant wrapped securely to maintain alignment, containment, and midline flexion of extremities; mimics the feeling of physiologic flexion provided by the uterus.

Elongated sidelying – like a cross cradle position for breastfeeding; infant on side, head higher than hips; ear, shoulder, and hip facing toward ceiling and aligned; trunk elongated to enhance tidal volume; supports physiologic stability, endurance, and helps regulate milk flow.

Typical development:

Bursts, pauses, and suck-swallow-breathe patterns emerge with advancing PMA and are adversely affected by co-morbidities. These are general explanations of the terms.

Rooting reflex – turning the mouth in the direction of a tactile stimulus, prior to initiating sucking.

Burst-pause pattern – a series of sucks, followed by a series of breaths, followed by a series of sucks and so forth, in a "pattern." With a "stable" burst-pause pattern, there is sufficient depth and frequency of breaths to permit the subsequent sucking bursts to then occur without the need for an urgent breath.

Sucking rate (nutritive) – approximately one suck per second; may be altered by co-morbidities or purposefully by the infant.

Sucking burst length – variable, depending on co-morbidities and PMA; prolonged and continuous sucking without a stable burst-pause pattern can lead to incoordination and bolus misdirection.

Suck-swallow-breathe coordination – *timing and integration of sucking, swallowing, dynamic airway adjustments, and breathing without physiologic stress and/or airway invasion.*

Q: What is common practice in your unit to support the oral and pre-feeding skills for the infants with delayed introduction to oral feeding?

A: I like to conceptualize the feeding-related services neonatal therapists provide in the NICU as "feeding readiness" and "supporting safe and functional oral feeding" to help neonatal nurses and neonatologists understand how we are uniquely prepared to support both preterm and sick term infants in the NICU. We begin early to foreshadow for parents the swallowing, breathing, and postural skills needed, and help families through guided participation support those components in simple ways during interactions with their infant (Shaker, 2018; Shaker, 2013c).

If they were not born too soon, preterm infants would be in utero integrating their structurally intact aerodigestive system as early as 17 weeks of life, swallowing several ounces of amniotic fluid per day. Intrauterine motor learning and oral-motor learning provide the underpinnings that support oral feeding in the delivery room for term infants. That means fullterm newborns (40 weeks gestation) have had 23 weeks of intrauterine motor learning prior to "using" those skills at birth. For our preterm infants, every week early is an additional seven days of intrauterine learning lost. Even at term-equivalent, the preterm infant remains at a disadvantage.

In the NICU, we carefully structure experiences outside of the uterus that most closely align with the ideal intrauterine sensory-motor environment, create a positive oral-sensory environment, promote the oral-sensory-motor components that underpin future oral feeding, and provide cautious infant-guided experiences that support therapeutic swallowing experiences (Shaker, 2017b). Sick term and postterm newborns also may have co-morbidities that delay onset of oral feeding and create the need for therapeutic support.

Postural control and alignment, swaddled side-lying, elongation of the trunk for optimal tidal volume, facilitated capital flexion to promote the motor learning for hands to face and mouth, while maintaining physiologic stability, is the foundation. Once the infant is tolerating a dry pacifier with physiologic stability utilizing co-regulated pacing, therapeutic pacifier dips can provide opportunities for creating the motor maps for swallowing needed for future oral feeding (Shaker, 2017a). A tiny droplet of mother's milk or formula is placed on the tip of the pacifier and then offered via the infant's rooting response. We rest the infant to rebuild reserves and offer co-regulated pacing to assure that respiratory stability is fostered from moment to moment via a stable burst-pause pattern. Based on the infant's responses, we progress to oral feeding with very small amounts via a slow flow nipple. Careful titration of bolus size, support for the swallowbreathe interface, and physiologic stability all become essential components of our intervention that support infant-guided learning as co-morbidities permit. The infant's physiologic and behavioral communication should always guide us (Shaker, 2013a).

Q: In our NICU, there is the idea that oral feeding trials need to happen within a feeding "window" or there could be longer-term feeding issues. Any thoughts for or against this "window"? Or do we know the origin of this idea?

A: My conversations with neonatologists over the years suggest this paradigm is based on writings from Gesell back in the 1960s, who described a "critical window" for infants to learn to eat. At that time, NICUs were just being developed; there were no therapists as part of the neonatal team since the need for therapy support was not well understood. Many neonates did not survive, and those who did survive often had enduring developmental impairments.

Back then, NICU infants were not orally fed until term adjusted age or beyond (i.e., 40+ weeks) due to complex medical issues precluding oral feeding. Historically, during their typically prolonged hospitalization back then, neonates did not have developmental support to avert maladaptive sensory, sensory-motor, and oral-motor patterns that often evolved. Feeding techniques to "transfer volume" were common. Follow-up community Early Intervention, which today is available communitywide and immediately post-NICU discharge, was not established back then. NICU graduates and children with developmental needs often could not access therapy until 3-4 years of age and, by then, presented with longstanding feeding impairments and complex maladaptive behaviors. Parents, after discharge, had done the best they could without guidance from skilled therapists. "Not missing a window" by starting oral feeding by an arbitrary age became the "solution." That was then. This is now. Actually, the solution is providing the right kind of feeding intervention when the infant shows readiness.

Today, with the advent of neonatal interdisciplinary teams that include physical therapy (PT), occupational therapy (OT), and speech-language pathology (SLP), we can support readiness by maintaining and developing those systems for future oral feeding when co-morbidities safely permit. "Readiness" to orally feed is best determined, not based on an arbitrary date or age, but rather on clinical signs and behaviors in the context of that unique infant's gestational age (age at birth), history and co-morbidities. That can set the stage for success, by recognizing safety issues inherent with some co-morbidities and clinical presentations that should suggest caution. Parents can then learn that positive learning versus volume supports long-term success (Shaker, 2013b).

Does the team ask them to orally feed to not "miss a critical window"? Or does the team maintain the neonate's readiness with therapy support, to optimize safety and neuroprotection, by individualizing readiness? The fact that NICU infants "eat" and "are fed" and "transferred volume" does not equate to safe or neuroprotective feeding (Shaker, 2013a).

Q: We have an infant in our NICU who presents with a high-pitched sound on inhalation and congested/loud breathing on exhalation. What might be the reason?

A: Stridor may be iatrogenic (caused by postextubation, post-ECMO; post PDA ligation or repair to the aortic arch; post-emergent, prolonged, or repeated intubation; or due to resulting subglottic stenosis, for example), or it may be congenital (related to a vascular ring, idiopathic occurrence at birth without explanation, laryngomalacia, pharyngomalacia, and tracheomalacia) (Daniel et al., 2017). It sounds like you are describing inspiratory stridor. Inspiratory stridor can have varving etiologies, such as Extra Esophageal Reflux (EER) or Laryngopharyngeal Reflux (LPR), laryngomalacia, pharyngomalacia, or other alterations that may affect airway patency. With dynamic sucking, swallowing, and breathing, it is not uncommon for the underlying etiologies to increase risk for airway invasion during oral feeding (Jadcherla, 2020).

Stridor heard at rest may suggest a primary airway pathology and may be exacerbated with the aerobic demands of feeding, both at breast and bottle. Contrast that with stridor that occurs only during feeding, which may suggest either swallow-breathe incoordination, due to the tendency to inhale after the swallow, or perhaps attempts at airway closure in a protective maneuver due to bolus misdirection from above and/or below (Bhatt et al., 2018). Of course, as therapists, we do not diagnose airway problems. Describing what is heard, in the setting of that neonate's unique history and comorbidities, may assist the neonatologist and ENT (otolaryngologist) with their differential. It also helps the therapist consider the "whys" that may underlie the feeding and swallowing challenges that are observed.

In my experience with stridor, a clinical swallowing evaluation followed by an ENT consult and flexible scope at bedside can guide us to etiology and reinforce the benefits of a video-swallow study to objectify swallowing physiology and potential interventions. The ENT may see a reddened larynx, reddened vocal folds, or altered airway structures that may adversely affect swallowing physiology and inform our practice.

Neonates with stridor may misdirect refluxate from below or misdirect a bolus from above being swallowed. The co-occurring congestion at rest may suggest refluxate or saliva in the hypopharynx and/ or laryngeal inlet. If there is onset of congestion with oral feeding, that may suggest bolus misdirection related to suck-swallow-breathe incoordination or a combination of etiologies.

What you describe as noisy breathing on exhalation may be low-pitched stridor related to tracheomalacia or bronchomalacia, or perhaps prolonged exhalation (which an infant may be using to re-open the collapsing airway, to open the alveoli, and to add positive-end expiratory pressure (PEEP), if there is indeed some level of airway obstruction). The infant may also be trying to clear the congested material off the vocal folds or out of the supraglottic space. Just hypothesizing.

Other co-morbidities, if present, need to be correlated, though this may be an "isolated," altered airway problem. There are quotes around "isolated" as ENT colleagues have taught me that truly "isolated" airway problems are rare, since it is a dynamic system. Advocating for ENT consult would elucidate the integrity of the airway to assist you in your feeding and swallowing differential.

Q: We are looking to start Passy Muir[®] Valve (PMV[®]) trials in the NICU on the older BPD/RDS trach/vent patients. Do you have a protocol you would be willing to share? When to start? Candidacy requirements?

A: While neonates requiring tracheotomy are approximately 0.1% to 1.8% of NICU admissions (Lee et al., 2016), they have unique needs for developmental support. Most neonates with tracheostomies are very to extremely preterm, have very to extremely low birthweight, and may undergo tracheostomy for multiple indications.

Developing a team approach in the NICU to support our neonates requiring tracheostomy is key. The implications of tracheostomy for neonates are not always well understood by NICU staff. Benefits of a Passy Muir Valve for the preterm and sick newborn may not be considered by NICU staff due to lack of information. The nuances of the neonatal swallow and the potential impact of an open trach during oral feeding, in the setting of that neonate's co-morbidities, is not always readily apparent to the medical team and requires ongoing dialogue. Through dialogue about the PMV and case-by-case conversations, the NICU team may best appreciate its potential physiologic, developmental, and costsaving benefits.

A team approach to intervention best supports success and safety. Partner with the Respiratory Therapist (RT) to provide information and education for the team about normal infant swallowing physiology, alterations in anatomy and physiology due to tracheostomy, and the benefits of the Passy Muir Valve for early communication and swallowing integrity. Collaborating with the RT during therapy sessions enhances patient care and problem-solving. Start slowly, facilitate learning from each neonate, and share the successes with the entire team.

The Passy Muir website is a valuable resource. It provides multiple webinars, including one I created with a colleague on the use of the PMV in the NICU, specific to feeding and swallowing. It addresses key considerations in teamwork, typical neonatal diagnoses leading to need for tracheostomy, indications for tracheostomy in neonates, the impact of the need for NICU care, and pertinent swallowing physiology unique to newborns and preterms. It also discusses alterations due to tracheostomy, criteria for and contraindications to PMV trials, benefits of the PMV unique to neonates, protocol driven guidelines for non-ventilator and ventilator application in the NICU, and intervention as well. There are video clips of an infant with PMV trials and a swallow study with and without the PMV. Nationwide Children's Hospital also created a webinar for the Passy Muir website related to use of the PMV for language and communication with older infants' status post NICU. Other resources for you include a patient and family centered model of feeding and swallowing management for children with tracheostomies (Jackson et al., 2018).

Q: Can you share your feeding protocol for infants in the NICU requiring long-term ventilation via tracheostomy?

A: I don't follow a strict protocol as much as scaffolding – peel the layers as I go along and learn from the neonate, combining that with history and co-morbidities, asking more questions, and collaborating.

It is uncommon for a neonate in the NICU requiring long-term ventilation to be discharged as a full safe oral feeder, given typical complex co-morbidities. These indeed are often our most fragile NICU infants. Start with understanding that infant's unique co-morbidities that led to the need for long-term ventilation, such as persistent pulmonary hypertension, chronic lung disease, central hypoventilation, ventilatory muscle weakness, neuromuscular disorders, and/or lower airway obstruction, such as bronchomalacia or tracheomalacia (Pereira et al., 2020; Pereira et al., 2003). They create an even higher risk for the infant to safely tolerate oral feeding (Joseph, 2017; Pullens & Streppel, 2021).

Multiple additional factors that should be considered include level and mode of respiratory support in the setting of that neonate's respiratory history, the prerequisite neuromotor and oral-motor integrity, ability to swallow saliva, oral-sensory processing, non-nutritive sucking, as well as physiologic stability during interventions utilized to support these prerequisites, and whether they are emerging. Once these prerequisites are established, I would likely be considering appropriateness of, and tolerance for, the PMV to establish flow into the upper airway. Restoring this airflow promotes restoration of taste, smell, and subglottic pressure, which most optimally underpins swallowing; at this juncture, the process includes working closely with the neonatologist, ENT, pulmonologist, and the RT.

For those infants with readiness skills, and who are appropriate for and tolerate an in-line PMV (with MD approval), the next steps may include using the PMV in-line while providing pacifier dips, followed by very limited trace oral feeding experiences with the therapist using interventions (developmentallysupportive positioning, a slow flow nipple, coregulated pacing, and resting). Brief, cautious, interval motor learning is likely important to reduce artifacts in radiology. Ideally, an NICU infant's first oral feeding should not be in radiology. However, this must be carefully and cautiously balanced with that infant's risk for, and ability to tolerate, airway invasion, especially from a pulmonary perspective.

In radiology, I have seen improved swallowing physiology with the PMV in place for these complex neonates. When a tolerated PMV restores the fundamental underpinnings for swallowing, we see improved physiology for suck-swallow-breathe coordination.

Q: Do infants with tracheostomy in the NICU need to tolerate a PMV before PO trials are started? Is a swallow study needed at some point?

A: If a PMV is an option based on etiology for tracheostomy and clinical status, my clinical experience suggests that establishing tolerance of a PMV before oral feeding trials are initiated in the NICU population is optimal. For both vented and non-vented neonates, the PMV appears clinically to improve swallowing integrity and swallowing physiology under fluoroscopy. However, a definitive relationship between swallow function and use of a one-way valve has not yet been established in the literature, especially for neonates (Zabih et al., 2017).

The neonate's co-morbidities and the reason for the tracheostomy are the starting point for our differential. Was the tracheostomy placed due to need for long-term ventilation, or were there any airway pathologies? Might they preclude tolerance of a PMV? When was the last time ENT saw the infant to assess airway integrity?

Most tracheostomies in patients in the NICU are performed in cases of chronic respiratory failure requiring prolonged mechanical ventilation or upper airway obstruction related to structural airway abnormalities (Isaiah et al., 2016). Chronic lung disease (CLD) is most often the underlying cause for prolonged mechanical ventilation, with extremely low birthweight and multiple failed extubations predicting the need for tracheostomy in neonates (Viswanathan et al., 2013). Structural airway abnormalities in the neonate may include subglottic stenosis, Pierre Robin sequence, tracheomalacia, vocal fold paralysis, or craniofacial syndromes. Neonates requiring tracheostomy often have other issues and multiple co-morbidities (gross and fine motor delays; altered postural control; sensory, oralmotor, and neurologic deficits; or gastrointestinal issues) that need to be considered regarding readiness to feed. If co-morbidities do not preclude a PMV trial, there is discussion with the team, especially the RT, about readiness, benefits for that neonate, and a timeline.

The neonatal swallow is highly pressure and sensory driven. This is especially critical for those neonates trached in the delivery room, who are chronically vent dependent from birth, and who then have no previous motor learning about swallowing with a normal aerodigestive system. With an open tracheostomy, pressures within the aerodigestive system (subglottic positive pressure, negative esophageal pressure, and intra-oral pressures) are altered. Restoration of these pressures via a PMV allows exhaled air to pass into the upper airway and may improve bolus control along the entire swallow pathway for the neonate. Intraoral airflow facilitated by the PMV may increase awareness: therefore, management of oral secretions, as well as restoring taste and smell, may help "guide" the neonatal swallow.

My goal in the NICU is to initiate PMV trials following our NICU protocol, which considers etiology for tracheostomy placement and clinical status, and then problem-solve with the RT. We work closely with ENT and Pulmonology to problem-solve those infants who are not progressing as we would expect. In our NICU, our criteria include post-initial tracheostomy change by at least seven days or greater, medically stable, awake and engaged, patent upper airway, reasonably able to manage oral secretions, trach collar or HME, or typically the following lower ventilator settings: Fraction of Inspired Oxygen (FiO₂) < 50%, PEEP < 10, and PIP < 40 cmH₂0.

In our NICU, the ENT typically places a Bivona Flextend TTS (Tight to the Shaft) tracheostomy tube; the cuff rests tight to the shaft of the tube, with the profile of an uncuffed tube. Our ENTs tell us that this allows for a variety of airway management needs. The TTS cuff can be inflated with water to help seal the trachea for a ventilated neonate if needed, but in our NICU even with ventilated neonates, the cuff is typically deflated. If cuff inflation is required, it is unlikely that the neonate would be tolerating the required lower ventilator settings for PMV trials. If the neonate was tolerating the lower ventilator settings, the RT would suction and deflate the cuff very, very slowly to help the infant adjust to the change and suction post cuff deflation. When readiness is then established, the RT and therapist proceed with a PMV trial, using the PMV®007 (Aqua color™) in-line with the vent and the PMV[®]2001 (Purple color[™]) for non-vent dependent neonates. It is important to start with a secure, swaddled, developmentally supportive position; offering a pacifier or the infant's own hands to mouth; and rhythmical vestibular and tactile input to optimize state regulation and provide a positive experience. Visual engagement and a familiar voice from the parent and the therapist often help to calm and reassure the infant. This step may take several sessions, depending on that neonate's unique history, co-morbidities, and age. Neuroprotection and infant-guided progression are essential along the way. The newness of restored airflow into the upper airway may be an unfamiliar and, at times, somewhat frightening sensation for the neonate. If the infant senses secretions and coughs for the first time, that event may surprise the infant; reassurance is often successful. Short daily trials to gain comfort with sensed secretions and airflow into the upper airway are offered and progressed in terms of frequency and length based on the infant's communication and tolerance.

Then, if co-morbidities and readiness safely allow, and with the PMV donned, we begin with offering pacifier dips. Once pacifier dips are tolerated, this is followed by cautious experiences with limited, brief therapeutic oral feeding trials with interventions (developmentally supportive positioning, single sips via a slow flow nipple, co-regulated pacing, and resting). Once the neonate has some careful infantguided experience with swallowing nutritively with the therapist, we then objectify swallowing physiology in radiology, due to the high risk for silent aspiration in the neonatal population (Ferguson et al., 2015). carefully plan the study to allow imaging both with the PMV donned and doffed, gathering data and providing insights for the medical team and nursing staff related to observed benefits of the PMV. This process is always tailored for each neonate through collaborative team problem-solving.

Addressing some of the more prevalent challenges faced in the NICU as it pertains to feeding considerations and tracheostomies, this discussion provides an overview of protocol and therapeutic interventions. With the prevalence of aerodigestive challenges leading to feeding and swallowing difficulties in sick term and preterm infants in the neonatal intensive care unit (NICU), this discussion challenges the clinician to use a problem-solving, critical thinking approach with an emphasis on individualizing the treatment plan with neonates.

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Real Talk: Problem-Solving Passy Muir® Valve Use in the Pediatric Population

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

Questions frequently arise regarding the use of the Passy Muir[®] Valve (PMV[®]) with the pediatric population. Unfortunately, there is a paucity of research in this area and clinicians frequently must rely on lessons learned and shared by seasoned clinicians. Another method is participating in continuing education that is specific to the area of pediatric tracheostomy. Following is a series of questions and answers which begin to address considerations for problem-solving before, during, and after use of the Passy-Muir Valve.

Considerations for the Initiation of PMV Use

Q: Where do we begin?

A: Well, in order to problem-solve PMV use with pediatric patients, the clinician should have a good understanding of the fundamentals of tracheostomies, ventilators, and the anatomy and physiology of respiration in the pediatric population. The clinician may accomplish competency by taking continuing education courses, reading the latest research regarding PMV use with adults and pediatrics patients, establishing specific competencies for working with patients following tracheostomies and mechanical ventilation, and forming a tracheostomy multidisciplinary team for tracheostomy management. The team should establish a best practice guideline for the facility. This team may include respiratory therapy (RT), ENT, pulmonology, neonatologist, ICU attending (CICU, PICU), and speech-language pathologists (SLP).

Clinicians should be aware of the resources that are available to them. From online continuing education to published research, clinicians do have options. I would like to share about textbooks that are available and may help the clinician understand the basics with regard to patients who are tracheostomy and ventilator-dependent. The highly regarded tracheostomy textbook, *Communication and Swallowing Management of Tracheostomized and Ventilator Dependent Adults*, by Marta Kazandjian, MA, CCC-SLP, BCS-S, CPT-EFS and Karen Dikeman, MA, CCC-SLP, is now in a third edition and titled Communication and Swallowing Management of Tracheostomized and Ventilator Dependent Individuals, as pediatrics has been added to this comprehensive review for tracheostomy and

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ventilator management. I had the honor of writing the chapter, "Management of Tracheostomized and Ventilator Dependent Pediatric Patients," which provides a detailed resource for both new and experienced clinicians working with infants and children who have a tracheostomy and/or ventilator dependence. The chapter presents an overview of prenatal and postnatal airway development, medical diagnoses affecting breathing and swallowing, and differences in the pediatric tracheostomy patient population as it relates to tracheostomy and ventilator dependence.

Q: So we have read and studied all about **PMV** with pediatric patients who are tracheostomy and ventilator dependent, but in practice, we may run into barriers for **PMV** application. How should we begin to address those barriers?

A: PMV application changes the dynamic of the patient's breathing. With PMV application, the patient requires cuff deflation, and the patient exhales exclusively out of the mouth and nose. This change in breathing, particularly for a ventilator dependent patient, may cause some physicians and clinicians to be reluctant to trial a PMV with a patient. The more you can educate yourself, the more you can educate the team on the benefits achieved with PMV use, the fewer barriers you will find. It is important to establish a team of physicians and clinicians, and to establish best practice guidelines for your facility, in order to ensure that everyone is on the same page in terms of candidacy and safety for PMV use with your patients.

Q: What is the youngest age of a patient who can use a PMV?

A: There is no specific age criteria. Older children have larger airways and may tolerate PMV application better; however, many infants successfully wear the PMV (Brooks et al., 2020). Younger infants have smaller airways, so they may need more time to grow if the patient does not do well with initial PMV trial.

Q: What do you say when a healthcare professional or a parent asks, "why are we doing this" or "this is a baby; babies do not talk; why does the baby need a speaking valve"?

A: These are not uncommon questions, particularly when considering a PMV trial with an infant who is medically complex. I rarely call it a "speaking valve" for that reason. It IS a speaking valve, but to me it is just as equally important that the patient can normalize exhalation and have the benefits of secretion management. My answer to these questions tends to be specific to the person who is asking.

For parents, the most important reason for a PMV trial is to hear their babies coo, cry, and vocalize. Parents and babies develop bonding through touch and these sounds.

For a doctor, that may not be enough reason to do the PMV trial with a medically complex baby.

For example, I asked a PICU attending recently if I could do a PMV trial on one of his medically complex infants, and he said, "Can you explain the benefits at this point in his medical course?" My response to this question was to share that my purpose would be "to restore exhalation out of his mouth and nose which will help him sense his secretions in order to swallow or cough in response. This can reduce the need for suctioning (nose, mouth, trachea). In addition, it will allow for vocalization; we can hear him cry to alert us that he has a need (diaper change, hunger)." He said. "OK, but he had a rough morning, can we do it tomorrow?" Actually, after reviewing the patient's chart, I ended up deferring the trial for a few weeks because his CO₂ was high, and I wanted him to be successful with the PMV trial. Once he was more stable, we did the trial. He did well; we advanced PMV wear time, trained the caregivers, and he was discharged wearing the PMV with strict caregiver supervision.

Q: What do you say when one of your fellow healthcare professionals says, "I don't think this patient will do well with a PMV trial?"

A: Unfortunately, this also is not an uncommon scenario – preconceived notions before assessment. I explain that the physician has cleared this patient for the initiation of a PMV trial. I discuss the steps that we will take during the PMV trial to ensure that the patient remains stable and comfortable. I often say, "We will know pretty quickly if the patient will do well with the PMV trial, and if any signs of stress or difficulty breathing occur, we will immediately remove the PMV." It's a partnership among physicians, nurses, respiratory therapists (RT), speech-language pathologists (SLP), patients, and families, and we want all involved to support each other.

Q: Why is it important to understand the patient's indication for the tracheostomy?

A: Whenever I get a speech consult for a patient with a tracheostomy, the first question I ask during a chart review is "why did this patient need a tracheostomy?" There are three broad categories of indications for a tracheostomy, including respiratory failure; airway compromise, such as obstruction; and neurologic or neuromuscular diagnoses. Understanding the differences among these diagnoses will help the clinician understand how to address PMV application and feeding/swallowing.

Expectations Based on Etiology

Q: What do you expect when you see that the patient has the tracheostomy because of respiratory failure?

A: When patients have a tracheostomy for respiratory failure, they are likely ventilator dependent. Think about the respiratory system and ventilation. This patient was initially intubated with an endotracheal tube (ETT) because the patient could not breathe well without support from mechanical ventilation. Typically, these patients could not successfully extubate or breathe on their own with the ETT removal without ongoing assistance from mechanical ventilation. Therefore, these patients undergo a tracheostomy so that mechanical ventilation may be given through the tracheostomy tube, and the patient no longer must have the ETT inserted through the mouth or the nose. The indication for the tracheostomy should be found in the surgery note, if the clinician has access to that report in the medical chart. Otherwise, with a good chart review, the clinician may understand the medical course prior to the tracheostomy that led to the surgery.

Each patient has different mechanical ventilation needs depending on the medical history and respiratory status, and these settings are ordered by the physicians. The clinician will review the chart to determine the following ventilator settings that the physician has ordered for the patient: mode (pressure or volume control), respiratory rate, PIP (peak inspiratory pressure, for pressure control), PEEP (positive end-expiratory pressure), pressure support, tidal volume (for volume control), and FiO₂ (fraction of inspired oxygen). SIMV (synchronized intermittent ventilation) is a mode where the patient takes spontaneous breaths in addition to the ventilator breaths. On pressure control mode, the vent breath is the PIP, the spontaneous breath can be supported by the "pressure support" (a boost of pressure for the patient's own breath). The PEEP setting is the pressure that the vent delivers to keep the alveoli open and ventilated at the end of exhalation.

The Pulmonologist and the RT will be great resources to help the clinician understand the ventilator settings and why certain settings or adjustments have been ordered. Understanding the ventilator parameters and why the patient requires certain settings are the first steps for successful use of the PMV.

Q: What do you expect when you see that the patient has a tracheostomy due to airway obstruction?

A: These patients may or may not be ventilator dependent. I would want to learn where the level of obstruction is, then determine if it is oral, nasal, pharyngeal, laryngeal, or tracheal. The ENT notes should have that information. This information may help the clinician understand how that obstruction might impact the ability of the patient to exhale adequately out the upper airway when the PMV is applied. Think about obstruction at any of those areas of the upper airway - these patients cannot breathe adequately out of their mouth and nose, there is some level of narrowing or obstruction that prevents it. So, the patient needed the tracheostomy tube, which is below the level of the vocal cords, in order to "bypass" that obstruction. Therefore, when we are applying the PMV, we know that the patient may have difficulty exhaling through the upper airway.

At my pediatric acute care hospital, the RT and SLP measure transtracheal pressure for every initial PMV trial and as needed for ongoing trials. If the transtracheal pressure is too high with a PMV trial because of obstruction, the clinician may discuss this with the ENT and understand if there is any intervention that might improve PMV tolerance. For example, if the patient recently had surgery and there is upper airway swelling or edema, perhaps the patient will be able to wear PMV once the swelling has reduced over time. If the ENT plans to surgically repair the airway obstruction, then the clinician can trial the PMV again after surgery. Communicate with your team members!

When considering the use of transtracheal pressure (TTP) measurements, transtracheal pressure of < 10 cm H₂0 is considered ideal, indicating a patent airway; however, patients with TTP <15 cm H₂0 also may tolerate the PMV for shorter periods of time. If the patient's TTP is >15 cm H₂O, then it is likely they will not tolerate the PMV due to airway obstruction (Brooks et al., 2020). That pressure in the patient's airway is too high for comfort and safety.

Q: What do you expect when you see that the patient has a tracheostomy because of a neurologic issue?

A: I would expect that the patient needed the tracheostomy in order to provide mechanical ventilation but the pulmonologist, neurologist, or attending physician on the unit may explain the specific need for mechanical ventilation based on the specific neurological diagnosis. These children tend to initially have "healthy lungs" but need the ventilator because of the neurologic or neuromuscular disease compromising adequate respiration and ventilation. However, these patients may be at risk for pneumonia and potentially lung disease over time.

Tracheostomy Tubes and Cuff Management

Q: Let us talk about tracheostomy tubes. What are the biggest differences between adult and pediatric tracheostomy tubes?

A: At our institution, most of our children have Bivona tracheostomy tubes. These tubes can be cuffed or cuffless. The cuffed neonatal and pediatric Bivona tracheostomy tubes are inflated with water as opposed to air, as often seen in adult tracheostomy tubes. These cuffs are also tight-to-the-shaft, which assists with airway patency during deflation. Pediatric tracheostomy tubes come in smaller sizes (ie: smaller diameter) because pediatric anatomy is smaller. At our institution, most of the our pediatric tracheostomy tubes are single lumen, meaning that there is only an outer cannula, as opposed to the double lumen seen in most adult tracheostomy tubes, meaning that both an outer and inner cannula are used.

Q: Why would a patient need a cuffed tracheostomy tube?

A: The cuff is inflated on the tracheostomy tube in order to avoid a "leak" into the upper airway and to maximize ventilator support. A leak is the space between the tracheostomy tube and the trachea. If the cuff is deflated or the patient has a cuffless tracheostomy tube, the patient has space around the tracheostomy tube, allowing air to "escape" up into the upper airway. Patients with high ventilator settings need all the ventilator support to go directly into the lungs; therefore, physicians often do not want any air "escaping" into the upper airway for the patients with high ventilator settings.

However, a leak is important for PMV use as the air escaping through the patient's vocal cords, pharynx, nose and mouth helps with our SLP goals of talking and eating. As soon as the patient's ventilator settings are appropriate (PEEP 10 or less, PIP < 40 cm H₂0, and FiO₂ < .50), I start the discussion with the team regarding cuff deflation, PMV trial, and PO trial ("per os" or eating by mouth).

Q: What are some benefits of cuff deflation?

A: The same as the benefits of PMV use, only PMV placement magnifies the benefits. The benefits include increased upper airway sensation (nose, mouth, pharynx, larynx); better secretion management (can cough or swallow secretions when they are sensed); improved ability to taste and smell; improved swallowing function; and providing some increased ventilation from the upper airway (mouth and nose).

Q: What do you do when a team member says that the patient is not a candidate for a PMV trial because of a cuff?

A: I explain that for every PMV trial, the FIRST step is to deflate the cuff COMPLETELY when the PMV is placed in-line (in the ventilator circuit) or on the tracheostomy hub for non- vent dependent children. With the PMV on, the patient can no longer exhale out of the tracheostomy tube, and the patient needs the air to move AROUND the tracheostomy tube (between the tracheostomy tube and the trachea out through the larynx, pharynx, mouth, and nose. If the patient's cuff is inflated and the PMV is placed, that is extremely dangerous as the patient can inhale but not exhale.

Q: Do patients tend to tolerate cuff deflation?

A: Since I am conducting PMV trials on patients whose ventilator settings are not considered high, they do tend to tolerate cuff deflation. The respiratory therapist and I are very careful to ensure that the tracheostomy is suctioned pre and post cuff deflation, and we slowly deflate the cuff so that the patient can adjust to the change in the airway (having a leak with some air moving around the tracheostomy tube and up through the upper airway).

Q: How long should the patient tolerate cuff deflation before doing a PMV trial?

A: For many of our children, the PMV trial is the first time that the patient will have had a cuff deflation trial. For these patients, the RT suctions the tracheostomy before deflating the cuff, deflation is done slowly, the SLP supports the infant or child by offering calming techniques (swaddle, pacifier for infants, and distractions, such as singing or videos, as age appropriate). The RT suctions again after cuff deflation. If the patient looks good after cuff deflation, we immediately proceed with a PMV trial.

Q: What do you do if a physician or **RT** do not think that the patient will tolerate cuff deflation?

A: I would ask why there is that fear and ask if we can trial cuff deflation to see if that is the case. I also would underscore that this is with STRICT supervision by the SLP and RT. If the physician or RT is nervous about cuff deflation, and will not allow a PMV trial, I offer to supervise the patient during my session with the cuff deflated and closely monitor vitals (HR (heart rate), RR (respiratory rate), O₂ Sats (oxygen saturations)) and work of breathing. If the patient does well with cuff deflation, I ask for the patient to have short cuff deflation trials during the day. Once the patient demonstrates doing well with cuff deflation, I ask for a PMV trial, again.

Considerations for PMV Use and Cuff Management

Q: What do you do if you get a consult for a PMV trial with a patient who does not tolerate cuff deflation?

A: Since we do PMV trials with patients whose vent settings are considered low, they tend to tolerate cuff deflation. If, for some reason, the patient does not tolerate cuff deflation, I would want to be present for cuff deflation to understand why the child isn't tolerating it. How quickly was the cuff deflated? A quick cuff deflation can be stressful for a child. What was considered "not tolerating cuff deflation?" Often

the patient coughs with cuff deflation, but this is GOOD! The patient is sensing the secretions that are pooling in the airway and appropriately responding by coughing. If the patient truly does not tolerate cuff deflation (instability, stress signs), then I would defer the PMV trial, of course. I would ask the physician what we could do as a team to work towards cuff deflation.

Q: When do you advocate for cuff deflation? Do you advocate for cuff deflation without a PMV?

A: As soon as the patient is on the following settings: $FiO_2 < .50$, PEEP 10 or less, and PIP < 40 cm H₂O, I am advocating for a PMV trial. If the physician allows, then the cuff deflation will occur at the start of the PMV trial. If the physician does not want a PMV trial, I will ask for a cuff deflation trial.

Use of Transtracheal Pressure Measurements

Q: What if the doctor says that the patient has upper airway obstruction, so they cannot wear the PMV?

A: I always measure transtracheal pressure (TTP) with a manometer so I will know if the patient can exhale adequately around the tracheostomy tube and through the upper airway. The manometer measures TTP and tells the clinician about "airway patency," whether the airway is patent and open. The manometer is placed between the PMV and the patient and will give the clinician many different values. It has a pressure value for every movement or every pressure, such as inhalation, exhalation, coughing, and different vocalizations. Every movement that the patient makes may be reflected in the pressure value on the manometer. The value that is the most important to know shows if the patient can adequately exhale out of the upper airway with the PMV applied. This value is the number at the END of exhalation, which will be the patient's end-expiratory pressure or transtracheal pressure. If the patient cannot exhale adequately, the TTP will increase, and we will quickly remove the PMV. But it is critical that the TTP is measured with resting breaths, the patient calmly breathing, so the clinician knows that the manometer is indicating the true TTP.

Some children with upper airway obstruction can wear the PMV safely. Upper airway obstruction, such as grade 2 subglottic stenosis, may not be a contraindication for a PMV trial. If the clinician is testing transtracheal pressure via manometry, the clinician will know if the obstruction is too great to wear the PMV (Brooks et al., 2020). The TTP indicates the airway patency, and each patient must be evaluated individually.

Q: Do you measure transtracheal pressure for all initial PMV trials?

A: Always.

Q: Can you perform pressure testing via manometry with water filled cuffs?

A: Don't confuse measuring transtracheal pressure via manometry with measuring tracheostomy tube cuff pressure. Tracheostomy tube cuff pressure is most often measured by RTs to assess the amount of air that should be in the cuff. The pediatric tracheostomy tubes that we use most frequently at our hospital are Bivona pediatric tracheostomy tubes, and the cuffs are inflated with water. Our RTs do not measure tracheostomy tube cuff pressure with water filled cuffs. These cuffs are filled with sterile water, and the amount is usually determined by the RT.

Q: Why would the TTP be too high?

A: Sometimes the tracheostomy tube is too large in comparison to the patient's small trachea, and there is not enough "room" between the tracheostomy tube and the tracheal lumen. If the tracheostomy tube size is age appropriate, and the TTP is too high, the patient may have some level of upper airway obstruction that compromises the ability to exhale adequately with the PMV on. Measuring TTP is helpful during initial PMV trials because the clinicians will see immediately if the patient has adequate exhalation with the PMV on or in-line, before any instability occurs such as an oxygen desaturation or bradycardia.

Q: When do you alert the ENT and pulmonologist that you are concerned for the possibility of an unknown upper airway obstruction?

A: I alert the team if the tracheostomy tube has been downsized and the patient still has a high pressure or cannot vocalize with the PMV. If the infant is young, approximately newborn to one month, the airway may just be too small to tolerate the PMV at the time it was tried, and I would continue to trial maybe every other week or so as the patient grows. If the pressure is too high and there is no explanation, the ENT might want to do a bedside endoscopy or a sedated scope – direct laryngoscopy bronchoscopy (DLB) – to investigate the cause of the high pressure. The cause could be something as simple as a granuloma causing obstruction and resulting in the high pressure.

Q: Does manometry measure the leak that occurs with cuff deflation?

A: Yes, it measures the pressure within the trachea, transtracheal pressure, when the PMV is applied. If the "leak" (room between the tracheostomy tube and the tracheal lumen) is adequate AND there is no significant obstruction ABOVE the level of the tracheostomy tube (larynx, pharynx, nose and mouth), then that airway is "patent" and the TTP will be low.

Q: What do you do if the patient's TTP is too high?

A: If there is no known upper airway obstruction to explain the high pressure, and the tracheostomy tube is large, I ask the ENT and pulmonologist if the patient may be downsized to a smaller tracheostomy tube. Depending on the patient's age, size, and medical diagnosis, the team may be willing to try. If the patient is at risk for mucous plugging or has many secretions, the team may not want to downsize. The 3.5 tracheostomy tube is the smallest size that our physicians are willing to use because any smaller and there is a higher risk of mucous plugging.

Q: Do you ever drill holes in the PMV if the TTP is too high?

A: We do not drill holes for several reasons. That is a deviation from the manufacturer's guidelines, which can be a liability to the clinician. However, it is also unnecessary. One of the benefits of the PMV is to problem solve why the patient does not tolerate the PMV. For example, if the patient has a 4.0 tracheostomy tube and does not tolerate the PMV, a downsize to a 3.5 might allow the patient to wear it comfortably with this smaller tracheostomy tube. Sometimes a high TTP alerts the ENT that there is an unknown obstruction, such as a granuloma, and the ENT intervenes with a DLB to identify that obstruction and potentially impact the plan of care.

Ventilator Dependence and Impact on PMV Use

Q: Switching gears now from upper airway issues to lower airway issues. What do you do when a team member says that the patient is not a candidate for a PMV trial because of being ventilator dependent?

A: That actually happens quite often, and I review that the PMV was invented for patients with or without ventilator dependence. David Muir was the inventor and was ventilator dependent; he made this valve to go into his ventilator circuit. There are so many benefits to early intervention with PMV application with patients who are ventilator dependent. Using the Valve restores exhalation through the patient's upper airway and does not return exhalation to the ventilator. These benefits were highlighted earlier but include the ability to sense secretions in order to cough or swallow, sense the bolus during swallowing, vocalize, cry, talk, smell, taste, bear down for bowel movements, and to use the glottis to help engage the core for transfers. For these reasons, early intervention and application of the PMV benefits patients who are ventilator dependent and their caregivers greatly.

Q: At what point can speech therapy place the **PMV** without **RT** present for a patient on a ventilator?

A: Great question. I work in an acute care hospital, so there are always respiratory therapists on the units with children who are tracheostomy and ventilator dependent. RTs are always present for the initial placement and are present until we have accurately measured transtracheal pressure. RTs are present initially (during application) until the patient has demonstrated good use of the PMV over time (demonstrated by wear time of 20 - 30 minutes). Once the patient has demonstrated a patent airway (transtracheal pressure 10 or less is ideal), I let the RT on the unit know that I am going to place the PMV. If the RT wants to be present for application, they may; otherwise, I place it myself, if the medical team has agreed. However, this is in my facility. Each facility has their own policy and procedures. So, the role of the SLP and RT with Valve use may differ facility to facility. Be aware of what you have in place at your facility.

Q: Do you change the ventilator settings with PMV trials?

A: I do not. I believe that for adult patients, the ventilator settings may need to be changed for a variety of reasons. But it is important to understand the literature and the population that is studied in the literature. The clinician also must be familiar with the ventilator modes and settings used during ventilation. For example, adults who are on pressure control ventilation may require a different assessment than an adult on volume control ventilation. It also is important that we do not apply adult studies directly to pediatric patients and assume that it is the same. An adult who requires mechanical ventilation at the age of 65 is very different from a premature infant with bronchopulmonary dysplasia or chronic lung disease. These two types of patients cannot be compared. Our TTP measurements show that with a patent airway, the transtracheal pressure value is very close to the PEEP setting that the physician

does not want the PEEP decreased due to the risk that the patient will not receive the support that the lungs need. With a PMV trial, we must show that the patient is still receiving the ventilator support that the physician wants and the patient needs.

For most of our patients, the ventilator does not alarm when the PMV is in-line. If it did, the RT would be present to identify what the alarm is and to silence the alarm, when appropriate. If the ventilator continued to alarm during a PMV trial, which rarely occurs, the physician would need to write an order for settings that could be changed for alarm management during the trial; however, then it is imperative that appropriate adjustments are monitored, or it could be dangerous for the patient. The clinicians must be aware of all changes and baseline parameters to mitigate any risk of forgetting to adjust the settings back after the PMV trial.

Q: Can you use a **PMV** with a home vent that has single limb circuit?

A: Yes, hospital vents tend to be dual limbed and home vents tend to be single limbed. I would do a PMV trial with either circuit. But the clinician should understand that infants and children on hospital grade vents are sicker, requiring a more sophisticated ventilator, so a more conservative approach to PMV trials is important. This could mean longer supervision by RT and SLP. It also may cause shorter wear times (i.e., 5-10 minutes). It is important for the therapist to be familiar with the ventilator being used and to make appropriate recommendations based on the patient's needs and the ventilator brand. Some of the processes may be a bit different depending on the ventilator being used.

Q: What are the differences between the in-line PMV (Aqua Color™) and the PMV used for nonventilator dependent tracheostomy (Purple Color™)?

A: The shape. Both can actually be used in-line (in the ventilator circuit), but the aqua one is shaped so that it can be placed with typical ventilator adapters and circuitry (15/22 mm step-down adapters and corrugated tubing). The purple Valve has a more curved shape, so it requires a special adapter (22mm silicone adapter) to place it in-line (available at *www. passymuir.com/pmv_accessories*).

Generally speaking, physicians and RTs prefer fewer adapters. With fewer adapters, the circuit is not getting longer (more space between the vent and the patient). Considering this factor, the Aqua Valve is usually preferred for patients with ventilator dependence.

Q: Do you ever take the patient off the ventilator for a PMV trials?

A: Never. If the patient is ventilator dependent, I would always do PMV trials in-line so that the patient receives the vent support they need during the trial.

Q: Do you always partner with an RT for an initial PMV trial?

A: Always. RTs are always present, at least for the initial placement of PMV for patients with ventilator dependence. For patients with only a tracheostomy, the RT is either present or on the unit and alerted that I am doing a PMV trial.

Roles of the Team Members

Q: What about for outpatient settings where there is not an RT present?

A: That is a challenging situation. The answer to that question would be institution specific, and there should be a protocol or best practice guideline in place. Our RTs trial the PMV during outpatient clinic visits with both the RT and pulmonologist present. Transtracheal pressure is measured. If the pressure is within acceptable limits and the patient does well, the physician may order that the PMV be trialed in the outpatient setting with a trained clinician. For patients with ventilator dependence, it is ideal to have the SLP and RT present for the initial trial, however, that may not be readily available in the outpatient setting.

Q: Do all clinicians have experience with using the **PMV**?

A: Not all do. We are fortunate to have two or three RT educators who conduct the majority of the PMV trials with the SLPs. It is nice to have that consistency and knowledge base for PMV trials with our medically complex and fragile infants and children. If the RT educator is not present, I will do a PMV trial with the patient's assigned RT. In this scenario, if the RT does not have much experience with PMV use, I, as the SLP, take more of a lead on the placement, asking them to deflate the cuff, suction the tracheostomy tube, and other relevant steps. Then, their role is mainly to be there for any ventilator needs or if the patient presents with any stress signs with the trial. The roles of the RTs and SLPs during assessment can vary facility to facility. It is important to consider establishing a team of trained healthcare professionals to meet the needs of your patients.

The more the SLP can learn about mechanical ventilation the better equipped the clinician will be to work with the RT and "speak the same language."

For example, SLPs and RTs have different training, and each discipline brings different viewpoints to a PMV trial. Success occurs when the SLP has a good understanding of anatomy and physiology of the upper and lower airway, changes that occur with physiology and respiration during a PMV trial, and effects of the various ventilator settings on the patient's breathing. Each discipline benefits from understanding the skills that each team member brings to the assessment and treatment. Establishing a policy and procedure assists with designating the role of each team member.

Q: Which physicians do you involve when asking for a PMV order?

A: The surgeon who performed the tracheotomy (usually the ENT but on occasion it may be pediatric surgery), pulmonology for PICU, and the hospitalists for the units (i.e., Neonatology for NICU, attending physician in the PICU). We have a trach/vent acute care unit at our facility, and these patients tend to be managed by Pulmonology as the primary team.

Q: How involved are the nurses at your hospital with PMV trials?

A: Our nurses are always aware that the RT and the SLP are applying the PMV on the patient and are involved as much as possible. The nurses are helpful in supporting the patient during a PMV trial. Our nurses generally do not place the PMV, as this is usually done by our RTs and SLPs. But if the patient has demonstrated tolerance and safety with PMV trials, and the physician orders that the PMV may be worn with strict supervision from a caregiver or clinician, I will place a picture with instructions at the bedside for reminders, if the nurse wants to place the valve.

Use with High-Flow Nasal Cannula

Q: Do you place the PMV when the high-flow nasal cannula (e.g., OptiflowTM), is connected to the tracheostomy hub?

A: In my facility, I do not. Since we do not know the effect of high flow on the membrane of the PMV, we prefer removing the Optiflow and placing the PMV on the tracheostomy hub. If the patient requires supplemental oxygen (FiO₂ greater than 21%), I discuss with the RT could the option to change to a tracheostomy collar/mask to provide the FiO₂ needed. The mask would also be used for humidification, if needed.

Dealing with Anxiety

Q: What do you do to help the patient become less anxious with a PMV trial?

A: That is a huge challenge in pediatrics because infants and toddlers are too young to understand what is going on with a PMV trial; we cannot tell a one-year-old, "just breathe, relax, you're OK," or "let me know if this feels uncomfortable." For infants and young children, we have to watch for signs of difficulty, such as eyes widening, stress signs, or increased work of breathing. There are techniques that may help with PMV trials. Often the SLP and RT need to attempt PMV trial across multiple sessions in order to help the patient adjust to the difference in breathing. For infants, strategies may include offering a pacifier, swaddling, holding the baby, or placing the Valve during a drowsy state. For toddlers and young children, distraction techniques may include watching a video on a phone or tablet, singing or talking to the child to promote calm resting breaths, or placing the Valve during a drowsy state.

Q: Does the cuff need to be deflated in order to feed the patient?

A: I always advocate for cuff deflation (AND PMV) whenever the patient is eating or drinking because of the benefits. These benefits include increased upper airway sensation (nose, mouth, pharynx, larynx), so the patient can sense where the bolus is during oropharyngeal transit; improvement in the ability to taste and smell; and improved hyolaryngeal excursion, resulting in less likelihood of residue in the pyriform sinuses (Ongkasuwan et al., 2014).

Q: What do you tend to do first – a PMV trial or a PO trial?

A: I tend to do a PMV trial first since the patient will benefit from the PMV with the PO trial. If a physician is comfortable with a PO trial, but not a PMV trial, I would have a discussion as a team about the precautions that are in place during PMV trials and refer to our Best Practice Guideline or protocol to help advocate for a PMV trial.

Q: Does the inflated cuff prevent aspiration?

A: No, if the material is on top of the inflated cuff it is, by definition, already aspirated. I can see the benefit of an inflated cuff for patients with frequent emesis as the inflated cuff can slow down the movement of the emesis into the lower airway, and the clinician may be better able to suction the material as it slowly moves down the trachea, especially during cuff deflation.

Q: If the physician does not want to deflate a cuff, do you ever consider small amounts of PO (e.g., 5 - 10 ml) with an inflated cuff?

A: I would not love it, but I would try if the physician ordered. To me, if the patient needs that level of respiratory support (all the ventilator support with no leak), then I would anticipate that it would be difficult for the patient to do well with the demands of PO feeding, particularly infant feeding when pauses in breathing occur approximately once a second.

Q: Do you do a Modified Barium Swallow study (MBS) before doing a PO trial?

A: I do MBSs on almost all my patients with tracheostomies, but the timing is important. We want our patients to do well on the MBS, so the more experience that the patient has with PO prior to the MBS, the better. If I need to test or prove the benefits of cuff deflation or PMV on swallowing, the MBS is the best way to demonstrate that.

Q: Would you do a PO trial on a patient with a PEEP higher than 10 cm H_20 ?

A: Generally speaking, my parameters for initiation of PO or PMV are the same, PEEP 10 or less, FiO₂ .50, and PIP <40 cm H₂0. If there is a specific patient with higher settings and the physician wants a PO trial, I would just document that this is a deviation from our Best Practice Guidelines and provide the rationale for the trial on these higher settings.

Conclusion

While we still have much to learn as it relates to working with the pediatric population, especially the medically complex and fragile infants with tracheostomies, clinicians who are using the PMV with this population continue to inform our practice with their clinical experience and research. The more that we address the needs early in the patient's care, the better chance the patient has to feed, manage secretions, and communicate. Understanding the physiology and pathophysiology of respiration and swallowing are critical to providing best practices. Being informed of how normal infant anatomy and potential upper airway obstruction impact airway patency are key to successful Valve placement. Providing access to the upper airway will enhance overall care and progress of the patient. If a facility has established a team, policies and procedures, and a best practice guideline, then managing this special patient population will be possible when using a PMV during mechanical ventilation, PO, and communication.

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Clinical Hot Topic Box

Carmin Bartow, MS, CCC-SLP, BCS-S

Additional swallowing intervention

In addition to use of the PMV to aid swallow function, the speech-language pathologist (SLP) may implement compensatory strategies and rehabilitative swallowing therapy. Therapy recommendations are individualized and are typically based on the findings from an instrumental swallowing assessment, such as the Videofluoroscopic Swallowing Study (VFSS) or Flexible Endoscopic Evaluation of swallowing (FEES®). The plan for intervention is developed and prescribed for an individual patient, involving thorough review of the patient's history, diagnosis, and physiologic changes identified during assessment.

Therapeutic considerations may include any of the following:

- Compensatory strategies
 - o Postural head, neck, & body changes to improve airway protection or bolus flow.
 - Head turn, chin tuck, head tilt
- Therapeutic maneuvers to reduce aspiration risk and improve bolus flow.
 - o Alternating liquids and solids
 - o Multiple swallows per bolus
- Diet modification.
 - o Altering food and liquid textures to reduce aspiration risk and improve bolus flow, such as the use of thickened liquids or soft foods
- Rehabilitative exercises
 - o Planned, structured, and repetitive physical activities for the purpose of improving flexibility, strength, and speed, of specific muscles or muscle groups for a specific purpose, including improving endurance.
 - o For dysphagia, this includes targeted exercises to improve the physiology of swallowing.

Featured Authors

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Carmin Bartow is a speech-language pathologist (SLP) with over 20 years of clinical experience treating patients in acute care. She has special interest in swallowing and swallowing disorders, head and neck cancer, and tracheostomy and mechanical ventilation. She was instrumental in developing the tracheostomy team in her previous position as an SLP at Vanderbilt University Medical Center. She is frequently an invited speaker at both the state and national levels and has authored a variety of papers. She is currently with Passy-Muir, Inc. as a full-time Clinical Specialist.



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.



Buffy Buchannan, MS, CCC-SLP

Buffy Buchanan is a speech-language pathologist (SLP) with 20 years of experience evaluating and treating a variety of patients in a level III trauma acute care hospital. She specializes in dysphagia management for the patient populations who are critically and neurologically ill, as well as tracheostomy and ventilator dependent. Buffy received her Master of Science degree from West Texas A&M University and is the speech-language pathology supervisor at Northwest Texas Healthcare System. She is proficient in instrumental swallowing assessments (FEES and VFSS). She served the lead role in the development of the first interdisciplinary tracheostomy team for an acute care hospital in the U.S. She continues to serve on the tracheostomy team and collects ongoing data for program development and improved process standards.



Hao Chen, RCP, RRT

Hao Chen is a Respiratory Care Clinical Supervisor at Barlow Respiratory Hospital. For the past 23 years, he has served patients weaning from prolonged mechanical ventilation and provides guidance in ventilator weaning troubleshooting. As a member of the Respiratory Therapy/ Rehabilitation team, he implements Passy Muir Valve for ventilator weaning and contributed towards the hospital's designation as a Passy Muir Center of Excellence. Hao Chen is a Registered Respiratory Therapist and graduated from Valley College, Los Angeles CA.



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David Shane Harper, PA-C, MPAS, DFAAPA

Dr. Harper started his career in medicine at age seventeen as a nocturnal EKG tech in rural Texas. He obtained his BS in respiratory care and eventually became a Physician Assistant specializing in Trauma/Surgical Critical Care. Currently, Dr. Harper is a faculty member of the Texas Tech Department of Surgery while serving as the Medical Director of the Surgical Intensive Care Unit at Northwest Texas Hospital, tactical medical officer for the S.W.A.T. Randal County Sheriffs Office, founding Editor-in-Chief of the West Texas Journal of Medicine and maintains several academic appointments. He has been an invited lecturer on a variety of critical care issues from the local to national level, is extensively published and has authored a chapter for *Interventional Critical Care: A Manual for Advanced Practice Providers*.

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Ashley M. Lopez is a board-certified specialist in swallowing and swallowing disorders. She currently is a medical speech-language pathologist at Houston Methodist Continuing Care Hospital in Houston, TX. As the lead clinician for the rehabilitation team, she strives to provide evidence-based practice for patients following tracheostomy and mechanical ventilation, with a special emphasis on dysphagia management. She is an ASHA Leadership Development Program alumni and an inaugural recipient of the Early Career Professional certificate in 2020. She currently serves as the Vice President for Social Media for the Hispanic Caucus and is a continuing education (CE) content manager for ASHA SIG13.



Marilouise E. Nichols, MS, CCC-SLP

Marilouise Nichols is a medical speech-language pathologist in Houston, Texas. As a 2013 alumna of ASHA's Minority Student Leadership Program, Marilouise demonstrated core leadership practices. She currently is a member of ASHA's Healthcare Leadership Development Program 2021 cohort, a program of selected professionals with leadership potential and has been recognized with ASHA's 2020 Distinguished Early Career Professional Award, an award and certification for those ASHA members who excel in leadership, volunteering, or advocacy at state or national levels. Additionally, she is graduate clinical educator and part-time instructor. Marilouise also serves on the Board of Directors for NBASLH (National Black Association for Speech-Language and Hearing).



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.



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Faith holds a master's degree in speech-language pathology from Portland State University (PSU). She is full-time staff and a clinical supervisor at the Portland VA Medical Center. She is also Adjunct Faculty at PSU and an ASHA STEP Mentor. Her clinical interests include validated tools to interpret instrumental studies for voice and swallowing, implementation and translational science, and increased representation of ethnically and racially diverse clinicians.



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COMMUNICATION AND SWALLOWING MANAGEMENT OF TRACHEOSTOMIZED AND VENTILATOR-DEPENDENT INDIVIDUALS



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