The Relationship Between Cough Peak Flow Values and Dysphagia in Individuals in the Acute Care Population

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ABSTRACT

Swallowing is a complex process that involves multiple muscles and nerves that are essential for adequate nutrition and hydration. When this process becomes impaired, dysphagia can occur. Dysphagia is common among elderly and hospitalized patients. It can result from neurodegenerative conditions, trauma, aging, or respiratory disease. Dysphagia may be acute, chronic, intermittent, or persistent. It can reduce quality of life, compromise nutrition, and increase the risk of aspiration.

Normal swallow function consists of the delicate balance of swallowing and breathing in order to protect the airway from invasion of food and liquids. Respiratory-related diseases can increase the risk for this process to become impaired. Chronic obstructive pulmonary disease (COPD) is a life-threatening condition characterized by chronic obstruction of lung airflow. There is growing evidence that supports the relationship between COPD and dysphagia.

Coughing serves as a critical mechanism for airway protection by clearing aspirated material. Recent studies have highlighted the utility of measuring cough strength, including the use of handheld devices, as an approach to dysphagia management. This study aims to evaluate voluntary cough strength and examine its relationship with dysphagia in hospitalized individuals with COPD.

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DEDICATION

This dissertation is dedicated to my daughter, Merritt Anne Cottle. You are my proudest accomplishment. I hope this achievement shows you that with hard work, faith, and perseverance, anything is possible. Always remember that I will be your biggest cheerleader, supporting you in every dream you pursue.

Chapter I

Introduction to the Study

The ability to swallow is critical for individuals to receive adequate nutrition and hydration. Enjoying a meal or coffee may seem simple, but the act of swallowing is a complex process that involves a variety of muscles and nerves. This complex process can become impaired due to several reasons including neurodegenerative conditions, trauma, aging, and respiratory diseases. Difficulty swallowing may be acute, chronic, intermittent, or persistent (Azer et al., 2023).

Dysphagia is a symptom of impaired swallowing that is common in elderly and hospitalized patients. It occurs in 1 in 25 adults and over half of Americans over 60 years old (McCarty & Chao, 2021). It is common for speech pathologists to evaluate and treat dysphagia in the acute hospital setting. A recent survey revealed that 90% of clinicians reported that swallowing disorders were one of the top five areas which they most frequently treated (American Speech-Language Hearing Association [ASHA], 2023a). Thorough examination and medical history information are important in determining the cause of dysphagia. Dysphagia can reduce quality of life, compromise nutrition, and increase the risk of content entering the airway. Impairments of swallowing increase the risk of aspiration and the likelihood of pneumonia. Aspiration pneumonia was associated in 48.2% of patients discharged from the hospital with dysphagia (Bosch et al., 2022).

Coughing is a symptom associated with dysphagia, reflecting the close physiological relationship between swallowing and coughing. Both functions play a critical role in airway protection. Normal swallowing prevents material from entering the airway, while coughing serves to expel any aspirated substances. An effective cough is necessary for clearing liquids and solids from the airway, thereby reducing the risk of complications. Recent research has increasingly focused on the role of cough measurement in dysphagia management, with several studies highlighting the practicality and cost-effectiveness of handheld devices for assessing cough strength. This study aims to evaluate voluntary cough strength and explore its relationship with dysphagia in a hospitalized population.

Chapter II

Review of the Literature

Normal Swallowing

The act of normal swallowing is critical for safe consumption of food and nutrition. Swallowing also plays a social role, bonding individuals together over a beloved meal. The process of swallowing is complex and requires neurological control within the brainstem, cerebral cortex, and cerebellum (Sasegbon & Hamdy, 2023). Numerous muscles throughout the face, pharynx, larynx, and esophagus are used during swallowing that are innervated by cranial nerves. The trigeminal, facial, glossopharyngeal, vagus, and hypoglossal nerves are involved in swallow function (Carnaby, 2012). The trigeminal nerve innervates the anterior 2/3 of the tongue and mandible and is responsible for tongue sensation and mastication. The facial nerve is critical for movement of the lips and cheeks and is important for keeping the bolus in the mouth. The posterior part of the tongue and oropharynx are innervated by the glossopharyngeal nerve. This nerve's roles include taste, sensation, gag reflex, and triggering the swallow (Carnaby, 2012). The vagus nerve is critical for the pharynx, larynx, and esophagus. It helps to protect the airway and assists in esophageal motility. Lastly, the hypoglossal nerve innervates the tongue and thus is involved in its ability to move food around the mouth.

The oral, pharyngeal, and esophageal phases comprise the act of swallowing. The oral phase can be subdivided into two phases: the preparatory and propulsion phases. During the oral preparatory phase, the bolus is taken into the mouth from a cup, straw, utensil, or hand. The bolus is held in the anterior portion of the mouth or against the hard palate. The soft palate is depressed to prevent material from spilling into the pharynx. During the propulsion phase, food and liquids are transited from the oral cavity to the pharynx as a voluntary process through coordinated movements of the oropharyngeal muscles (Azer et al., 2023). The tongue elevates to move the bolus posteriorly into the pharyngeal space. The soft palate elevates to seal the nasopharynx and prevents material from entering the nasal cavity and allowing the bolus to move towards the pharynx.

While the oral phase is under volitional control, the pharyngeal and esophageal phases are reflexive in nature and largely involuntary. The pharyngeal phase is responsible for directing food into the esophagus and protecting the airway from aspiration by closing the laryngeal space. During the swallow, there are several coordinated movements that involve the closure of the larynx. This includes adduction of the true vocal folds, approximation of the false vocal folds, epiglottic inversion, and anterior movement of the arytenoids to approximate the base of the inverted epiglottis (Vose & Humbert, 2019). Laryngeal vestibule closure is achieved when there is no airspace in the vestibule because of complete contact of the arytenoids to the epiglottis base and full epiglottic inversion (Vose & Humbert, 2019). Epiglottic inversion is comprised of two distinct movements (Pearson et al., 2016). As the tongue base retracts toward the posterior pharyngeal wall, the epiglottis is moved into a horizontal position. The epiglottis is further inverted by the contraction of the pharyngeal constrictor muscles that moves the bolus inferiorly to the esophagus. The bolus is moved by the contraction of the pharyngeal constrictor muscles (Vose & Humbert, 2019). The pharyngeal phase is completed when the bolus descends through the upper esophageal sphincter into the esophagus.

The coordination of respiration and swallowing is critical for facilitation of airway protection to prevent aspiration. Inspiration or expiration occurs prior to the swallow with a period of paused breathing during the swallow. The involuntary pause in breathing is termed swallow apnea (Ghannouchi et al., 2016). Breathing is ceased during swallowing by epiglottic inversion and closure of the airway (Matsuo & Palmer, 2008). After the swallow, another inspiration or expiration event occurs. There are four respiratory-swallow patterns that can occur during consumption: expiration/expiration, expiration/inspiration, inspiration/expiration, and inspiration/inspiration (Martin-Harris et al., 2005). Typically, swallowing occurs during the expiratory period of respiration. This expiration-swallow-expiration cycle prevents contents in the pharynx from entering the airway (Yagi et al., 2017).

Swallow initiation timing varies across healthy individuals. In many cases, the bolus reaches the valleculae or further before the pharyngeal swallow is triggered (Martin-Harris et al., 2007). Swallow initiation can be influenced by bolus volume, viscosity, sex, and race (Bhutada et al., 2020). Higher frequencies of swallow initiation were found during thin liquid swallow tasks compared to solids. Later swallow onset occurred during sequential swallows as opposed to single swallows (Bhutada et al., 2020). Women are more likely to initiate the pharyngeal swallow beyond the ramus of the mandible compared to men. These factors should be considered during swallow assessments to avoid misdiagnosis. It is important to consider that delayed swallow initiation does not necessarily indicate dysphagia. Delayed swallow initiation and the presence of dysphagia are what can increase the risk for impaired swallow function and airway safety.

Dysphagia

When this process of swallowing is disrupted, dysphagia, penetration, or aspiration may occur. Many conditions can negatively affect swallowing including anatomical, neuromuscular, and inflammatory diseases (Azer et al., 2023). Oral phase dysphagia may include reduced labial seal with spillage of liquids from the mouth. Individuals may have difficulty chewing solids and containing liquids in the oral cavity prior to swallowing. As a result, the bolus may be lost by either spilling out of the mouth or into the pharyngeal space. Reduced mastication or pocketing of solids can also occur secondary to impaired control of the tongue and dental impairments (Dewan, 2024). Dental impairments include poor oral hygiene and missing teeth. Adequate tongue movement is critical during the oral phase. Reduced tongue strength can impact bolus formation, control, and propulsion in swallowing. Decreased tongue strength can lead to pharyngeal residue caused by weak bolus propulsion and insufficient retraction to the posterior pharyngeal wall (Sugiya et al., 2022).

Pharyngeal phase dysphagia may include delayed swallow initiation, reduced constriction of pharyngeal muscles, or impaired laryngeal vestibule closure. Laryngeal vestibule closure is the first line of defense for preventing material from entering the airway (Vose & Humbert, 2019). Impairments in laryngeal vestibule closure can result from reduced epiglottic inversion, tongue base retraction, pharyngeal constriction, or laryngeal elevation. Laryngeal vestibule closure relies on adequate timing and range of motion. Swallowing deficits can result in delayed airway closure and increased risk for penetration or aspiration. Penetration refers to the entry of substances, such as secretions or food, into the larynx remaining above the vocal folds. In contrast, aspiration is the inhalation of oropharyngeal contents into the larynx and lower respiratory tract (Almirall et al., 2021). Aspiration events may lead to pneumonia depending on the amount and nature of aspirated material, the frequency of events, and the individual's response to the aspirated material (Almirall et al., 2021). A common symptom of aspiration includes coughing. A cough response is an individual's defense mechanism in expectorating unwanted material from the airway. Therefore, an effective cough is necessary to maintain safety and health when swallow function becomes compromised.

Changes in breathing patterns can compromise respiratory-swallow coordination and increase the risk for dysphagia and aspiration. Respiration and swallow discoordination occur when there is prolonged swallow latency, delayed swallow timing in the respiratory cycle, and inspiration following the swallow (Yagi et al., 2017). The occurrence of inspiration following the swallow increases with age and in patients with conditions such as Parkinson's disease and COPD. A higher occurrence of atypical respiratory-swallow patterns occurs with age (Martin-Harris et al., 2005). Swallow apnea, the brief cessation of breathing that occurs during swallowing, is a critical component of airway protection. In older adults, this process can become prolonged or uncoordinated due to age-related changes in neuromuscular and respiratory function. Furthermore, swallow apnea timing was significantly delayed in individuals 80 years or older (Martin-Harris et al., 2005).

Aging

Today, most individuals can expect to live past their sixties and beyond. By 2030, 1 in 6 people will be 60 years or older (World Health Organization, 2024). By 2050, this population is estimated to double and the number of individuals 80 years or older is projected to triple. Therefore, it is important for providers to be aware of age-related conditions and their impact on performance and activities of daily living. Cognitive changes can occur, including dementia, depression, and vestibulocochlear degeneration. Functional changes occur during aging such as reduced muscle strength, balance, mobility, and flexibility (Rodrigues et al., 2022). In particular, sarcopenia, which is defined as the age-related, involuntary loss of skeletal muscle mass and strength, is one of the major causes of functional decline and loss of independence in aging individuals (Watson, 2014). Sarcopenia can be characterized by low levels of muscle strength, muscle quantity, and physical performance (Köller, 2023). It is associated with increased mortality, reduced quality of life, and increased economic burden.

Dysphagia in the elderly population. Dysphagia is prevalent in the elderly population and those with medical conditions that result in reduced quality of life and medical consequences (Rivelsrud et al., 2023). Its prevalence among older adults can vary across healthcare settings. A meta-analysis performed by Rivelsrud et al. (2023) found that oropharyngeal dysphagia was present in 36.5% of patients in the hospital setting, 42.5% in the rehabilitation setting, and 50.2% in the nursing homes. Dysphagia has been associated with longer hospitalization, increased costs by 43.6%, and heightened risk of more medical complications (Attrill et al., 2018; Cohen et al., 2020). Aging and sarcopenia can increase the risk of dysphagia, as the loss of muscle mass in skeletal and swallowing-related muscles contributes to impaired swallow function (Sire et al., 2022). Age-related changes can alter specific components of swallowing, including reduced tongue control, diminished hyolaryngeal movement, delayed or incomplete laryngeal vestibule closure, weakened pharyngeal contraction, and reduced duration of pharyngoesophageal segment opening (Garand et al., 2022). Neural control of swallowing may become impaired due to age-related changes in the central and peripheral nervous system processing, causing slower reflexes, reduced coordination, and delayed swallow initiation (Rech et al., 2021; Robbins, 2013). Swallow function can be further compromised by neurological etiologies, respiratory changes, structural changes, and the physiological effects of aging.

Chronic Obstructive Pulmonary Disease

Chronic obstructive pulmonary disease (COPD) is a life-threatening condition characterized by chronic obstruction in lung airflow (Lin & Shune, 2023). COPD is the third leading cause of morbidity and mortality worldwide (Agarwal et al., 2023). Chronic inflammation of the airways leads to thickening of the airway walls, increased mucus production and changes in lung structure (Yawn et al., 2021). The inflammation and obstruction of the airways decrease the forced expiratory volume and tissue destruction leads to limited airflow and gas exchange (Agarwal et al., 2023). This condition results in progressive difficulty breathing due to persistent airflow obstruction (Itoh et al., 2013). COPD is suspected in individuals with symptoms of dyspnea at rest, chronic cough, and history of wheezing. Risk factors for COPD include smoking history, being older than 40 years of age, and exposure to pollution or occupational dust (Agarwal et al., 2023; Gentry & Gentry, 2017). As the condition progresses, gas exchange impairment is often seen with the risk of carbon dioxide retention (Agarwal et al., 2023). This condition is diagnosed by spirometry to assess airflow and severity. Other diagnostics include a 6-minute walk test, laboratory testing, and radiographic imaging (Agarwal et al., 2023). Individuals with advanced COPD exhibit poor nutrition due to dyspnea during eating, reduced appetite, decreased activity tolerance, and depression (Itoh et al., 2013). The presence of malnutrition and COPD may double the likelihood of prolonged hospital stay and hospital readmission within 6 months (Yogesh et al., 2024).

Dysphagia in patients with COPD. There is growing evidence that supports the relationship between dysphagia and COPD. It is suggested that individuals with COPD have difficulty breathing and coughing during meals (Lin & Shune, 2023). This could occur as patients with COPD demonstrate increased respiratory rate and altered breathing swallowing patterns (Cvejic et al., 2011). The presence of dysphagia may even lead to exacerbation of COPD due to the lack of coordination between swallowing and breathing (Steidl et al., 2015; Yagi et al., 2017). Mancopes et al. (2020) examined swallowing physiology during modified barium swallow studies on individuals with COPD. This study found that participants with COPD demonstrated incomplete laryngeal vestibule closure, longer time to achieve laryngeal vestibule closure, reduced pharyngeal constriction and pharyngeal residue. This could occur due to restricted hyolaryngeal movement and reduced laryngeal sensitivity. Swallow function was also examined during videofluoroscopy in patients with COPD and compared to normal control subjects (Cvejic et al., 2011). Penetration and aspiration events were higher in patients with COPD than healthy controls.

Assessment of Dysphagia

Dysphagia can increase the risk of complications such as malnutrition, dehydration, choking, pneumonia, and increased mortality (Sasegbon & Hamdy, 2023). There are various assessment methods used to identify the presence of dysphagia. These methods include screening tools, clinical swallow assessment, and instrumental assessments. Screening tools may include brief questionnaires or tasks to identify those at risk for dysphagia. Examples of screening methods include the Yale Swallow Protocol and the Eating Assessment Tool-10 (EAT-10). The Yale Swallow Protocol is a simple screen for aspiration risk in acute care patients. It is a pass/fail screen that is comprised of a cognitive screen, oral mechanism examination, and a 3-ounce water challenge (Ward et al., 2020). Although it has been found to be useful in determining aspiration risk in hospitalized patients, it cannot determine the presence of silent aspiration (Suiter et al., 2014). The EAT-10 is a 10 item self-assessment scale that can screen subjective dysphagia symptoms. Questions include dysphagia-related symptoms such as "Swallowing liquids takes extra effort," and "I cough when I eat" (Schindler et al., 2023). Individuals rate each question from 0-4 with 0 indicating no problem and 4 indicating a severe problem. The EAT-10 facilitates a patient centered approach to dysphagia care by increasing patient involvement and individualizing care (Bartlett et al., 2023). While the EAT-10 does not incorporate actual swallowing trials, it can be used as a preliminary screen for dysphagia (Zhang et al., 2023). However, this self-assessment scale may be difficult for those with comorbidities such as cognitive impairments and neurodegenerative disorders to complete.

Clinical swallow assessments, also known as bedside swallow examinations, are performed to further evaluate cranial nerve function and subjectively assess swallow function. It may often, though not always, be preliminary to an instrumental swallow assessment. The clinical swallow assessment is not equivalent to a screening tool. While a screening tool provides a pass/fail result and predicts the likelihood of a disorder, the clinical swallow assessment provides information to guide hypotheses related to the physiological nature of dysphagia that can be verified during the instrumental study (Garand et al., 2020). There are several components of a clinical swallow assessment. It includes a chart review, general observations of the patient's status, and patient/caregiver interview. General observations provide insight into the patient's posture and respiratory function. This is important to determine changes in status during feeding. A cranial nerve examination is performed to determine the presence of neurological dysfunction and its impact on swallow function. During a clinical swallow evaluation, the speech pathologist also observes the patient consuming a variety of textures and notes overt symptoms concerning possible dysphagia and aspiration. However, one major limitation to this type of assessment is its inability to accurately identify aspiration presence and swallow physiology impairments. The clinical swallow assessment cannot solely identify pharyngeal or esophageal physiology or guide effective treatment options (Garand et al., 2020).

Instrumental swallow assessments are considered the gold standard when evaluating and diagnosing dysphagia. Instrumentation, such as the modified barium swallow study and fiberoptic endoscopic evaluation of swallowing (FEES), allows direct visualization. During a

FEES examination, a flexible laryngoscope is passed transnasally and positioned to view the base of the tongue, pharynx, and larynx before, during, and after the swallow (Langmore et al., 2022). It allows direct visualization of anatomy and physiology, secretion management, penetration, and aspiration. There are a few limitations during a FEES. During the swallow, there is a "white out" period in which there is loss of visualization of structures during the swallow as a result of epiglottic inversion. It also does not provide visualization of the esophageal phase. The modified barium swallow study (MBSS) is a widely used videofluoroscopic assessment of the anatomy and physiology of swallowing. This study is performed in the fluoroscopic suite and permits visualization of bolus flow throughout the aerodigestive tract in real time (Martin-Harris et al., 2020). Barium sulfate is the contrast used in various consistencies to allow visualization of the bolus during fluoroscopy. The oral, pharyngeal, and esophageal phases of the swallow are assessed during this study. The oral phase components include lip closure, tongue control, bolus containment, mastication, bolus propulsion, and swallow initiation (Martin-Harris et al., 2020). The primary components comprising the pharyngeal phase include movement of the hyoid bone facilitating pharyngoesophageal segment opening, laryngeal elevation, laryngeal vestibule closure, tongue base retraction, and pharyngeal constriction. Lastly, the esophageal phase components include the degree and timing of esophageal bolus clearance (Martin-Harris et al., 2020). The presence, depth, response to penetration or aspiration, and result of compensatory strategies can be examined during the MBSS. Inter-rater agreement among clinicians is significantly greater when MBSS reports clearly articulate physiological impairments, compared to reports that concentrate on symptomatology (Slovarp et al., 2018). In order to optimize continuity of reports, it is important to consider utilizing a standard protocol or standardized tool when interpreting MBSS results (Martin-Harris et al., 2020).

Modified barium swallow impairment profile. The modified barium swallow impairment profile (MBSImP™) is a standardized tool for videofluoroscopic evaluation of swallow function (Martin-Harris et al., 2008). The MBSImP™ consists of 17 physiologic swallow components that are observationally scored across 12 swallowing tasks (see Table 1 for the list of components). Scores on the rating scale range from 0 to 2, 3, or 4 depending on the physiologic component. A score of 0 indicates no impairment while 2-4 indicate impairments depending on the specific component. The overall impression (OI) score is obtained for each component, which is the most severe score across all trials. The MBSImP™ is a valid tool with good interrater and intra-rater reliability between trained SLPs (Clain et al., 2022; Martin-Harris et al., 2008).

Table 1

Modified Barium Swallow Impairment Profile. (Martin-Harris et al., 2008)

Physiologic swallowing components
1. Lip closure
2. Hold position/tongue control
3. Bolus preparation/mastication
4. Bolus transport/lingual motion
5. Oral residue
6. Initiation of the pharyngeal swallow
7. Soft palate elevation
8. Laryngeal elevation
9. Anterior hyoid movement
10. Epiglottic movement
11. Laryngeal closure

12. Pharyngeal stripping wave
13. Pharyngeal contraction
14. PES opening
15. Tongue base retraction
16. Pharyngeal residue
17. Esophageal clearance in the upright position

Penetration-Aspiration Scale. The utilization of scales and tools for dysphagia diagnostics allows more objective findings rather than subjective. The Penetration-Aspiration Scale (PAS) was developed in 1996 by Rosenbek et al. It is an 8-point interval scale used to describe responses to penetration and aspiration events during an instrumental dysphagia assessment. The depth of bolus invasion and the patient's response to the bolus are two dimensions included in this scale (see Table 2). A score of 1 indicates no entry of material into the airway. Scores of 2-5 reflect penetration of material into the supraglottic space and as far as the true vocal folds, while scores of 6-8 indicate aspiration of material below the true vocal folds (Steele & Grace-Martin, 2017). A PAS score of 2 is not considered a threat to swallow safety (Allen et al., 2010). Scores higher than 2 (3-8) were seen in 56.5% of patients diagnosed with aspiration pneumonia (Seo et al., 2021). Therefore, a PAS score that is greater than or equal to 3 may be indicative of dysphagia. Clinicians typically apply the PAS while viewing the entire MBSS, assigning a maximum score for the patient's overall swallowing performance (Alkhuwaiter et al., 2022).

Table 2

Penetration-Aspiration Scale. (Rosenbek et al., 1996)

Score	Description
1	Material does not enter the airway
2	Material enters the airway, remains above the vocal folds, and is ejected from the airway
3	Material enters the airway, remains above vocal folds, and is not ejected from the airway
4	Material enters the airway, contacts the vocal folds, and is ejected from the airway
5	Material enters the airway, contacts the vocal folds, and is not ejected from the airway
6	Material enters the airway, passes below the vocal folds, and is ejected into the larynx or out of the airway
7	Material enters the airway, passes below the vocal folds, and is not ejected from the trachea despite effort
8	Material enters the airway, passes below the vocal folds, and no effort is made to eject

Instrumental Assessment of Dysphagia in Patients with COPD

Dysphagia was found to be highly prevalent in the COPD population. Nearly 85% of COPD patients that underwent a modified barium swallow study demonstrated dysphagia, with airway invasion present in nearly 56% of them (Good-Fratturelli et al., 2000). The PAS has been utilized during modified barium swallow studies for this patient population. When compared to healthy adults, patients with COPD had higher PAS scores, exhibited delayed swallow initiation, and increased oropharyngeal residue (Garand et al., 2018). COPD patients demonstrated structural mechanics such as increased kyphosis of the vertebrae in addition to swallowing deficits like increased pharyngeal shortening and an anteriorly positioned larynx during swallowing (Tadavarthi et al., 2021).

Most patients treated by medical SLPs have a diagnosis of respiratory disease, cerebrovascular disease, central nervous system diseases or hemorrhage/injury (ASHA, 2023b).

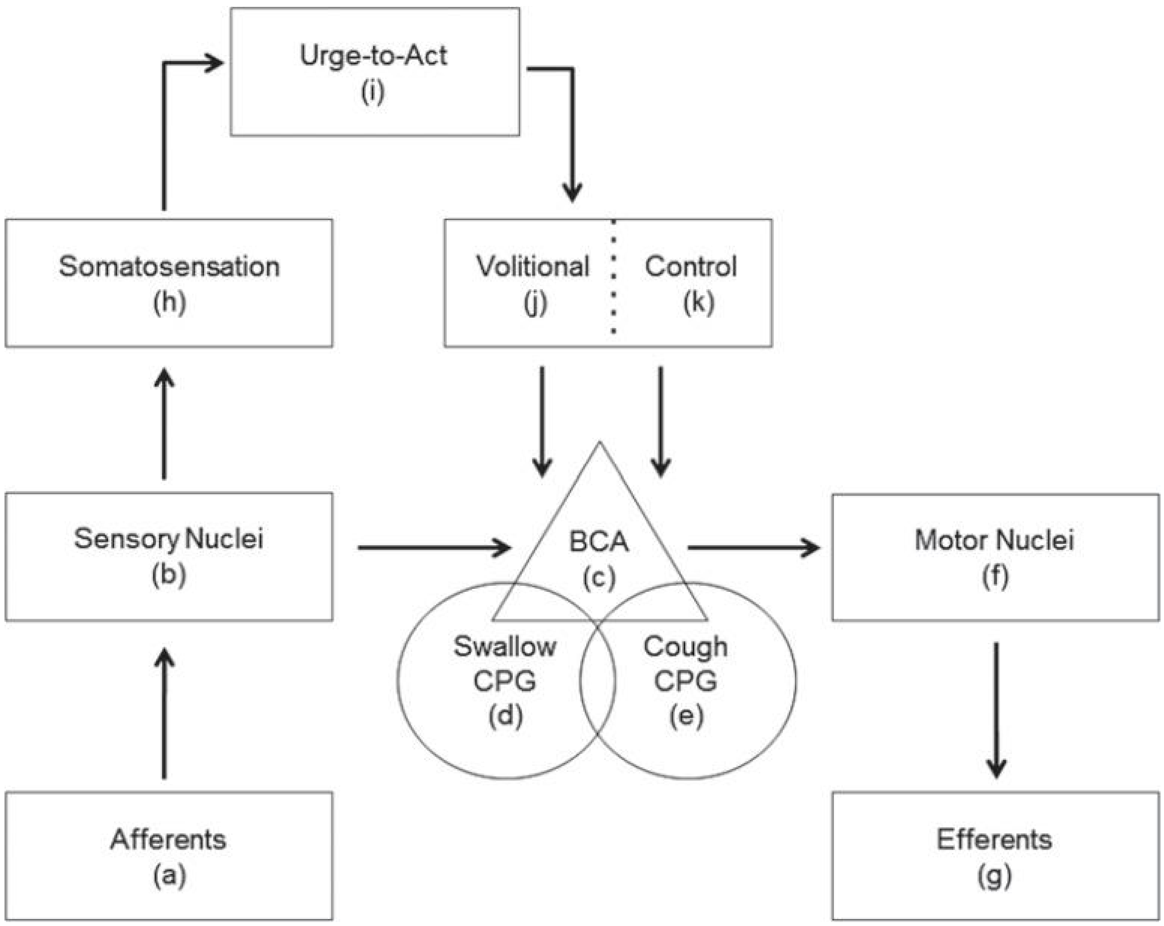
More than half of medical SLPs diagnose dysphagia in acute care patients (ASHA, 2023b); therefore, it is critical that swallowing is accurately assessed to avoid misdiagnosis or overrepresentation. Misdiagnosis and overrepresentation of swallow function are significant concerns in clinical practice. These concerns may consist of clinical assumption that dysphagia is more prevalent in certain populations without diagnostic information, leading to unnecessary interventions or modifications. Therefore, a multidimensional approach to assessing swallow function should be used given the complexity of patient populations and risks for adverse outcomes. In particular, deficits in airway protection can lead to health complications and reduced quality of life. One essential aspect of airway protection is coughing and thus should be considered during dysphagia diagnostics.

Coughing

Airway protection is complex and consists of adequate coughing and swallowing. Troche et al. (2014) developed a conceptual framework that represents swallowing and coughing along a spectrum of airway protective behaviors (see Figure 1). The authors stated that coughing and swallowing share afferents that are important to the initiation of behaviors. Afferent information is then sent to sensory nuclei in the brainstem (Troche et al., 2014). The behavioral control assembly receives the afferent information and exerts control over swallowing information and cough central pattern generators to produce the appropriate airway protective behavior. Troche et al. (2014) then explained that information sent to the motor nuclei is directed to the efferent nerves which results in execution of the behavior. This framework provides a comprehensive understanding of the cough and swallow mechanisms for effective intervention.

Figure 1

Proposed Framework of Airway Protection.



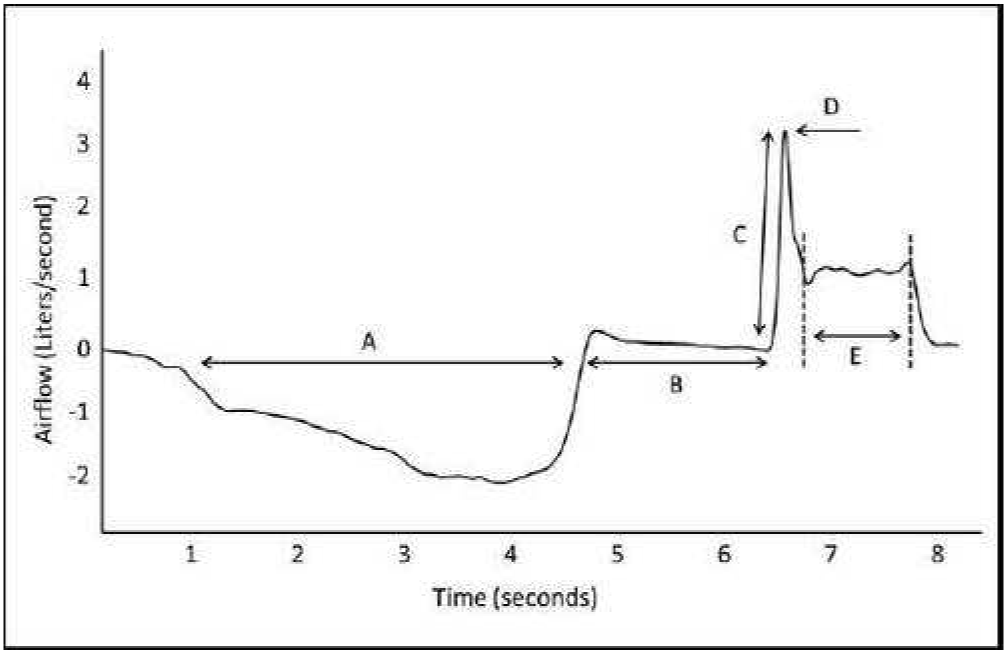
Note. This framework was developed in a previous study by Troche et al. (2014). It highlights the multisystem process of airway protection during the act of swallowing. BCA= Behavioral Cough Assessment; CPG= Cough Peak Flow.

A cough is a sensorimotor response to forcefully eject material from the laryngeal vestibule and airways (Watts et al., 2016). It requires precisely timed and sequential respiratory events from the diaphragm, chest, abdominal respiratory muscles, glottis, and parts of the brain (Brooks, 2011). An effective cough is critical in removing material from the airway.

A cough is comprised of three phases including the inspiratory, compression, and expiratory phases (see Figure 2). It involves precise coordination of respiratory and laryngeal musculature. During the inspiratory phase, the posterior cricoarytenoid muscle abducts the vocal folds (Hegland & Sapienza, 2013). This allows air to enter the lower airways. The lateral cricoarytenoid, interarytenoid, and thyroarytenoid muscles adduct and tense the vocal folds during the compression phase (Hegland & Sapienza, 2013). The adduction of the vocal folds creates increased tracheal pressure. Glottic closure is essential for coughing since the maximal level of intrathoracic pressure and efficiency of expiratory cough depends on the quality of glottic occlusion (Brooks, 2011). The expiratory phase occurs when rapid laryngeal opening is produced by the expiratory muscles and posterior cricoarytenoid. Expiratory peak flow is the highest point of expelled force during a cough (Hegland & Sapienza, 2013).

Figure 2

Cough Airflow Waveform



Note. This figure was developed by Hegland & Sapienza, 2013. Inspiratory Phase (A), Compression Phase (B), Peak Expiratory Flow Rise Time (C), Peak Expiratory Flow Rate (D), Post Peak Plateau Phase (E).

Cough Assessment. There has been growing interest in the evaluation and management of cough function. Coughing may be a common symptom that clinicians observe during a dysphagia evaluation as an indicator of airway invasion. The force of the cough is important as individuals with a weak cough have an increased mortality rate within 2 years (Hong et al., 2022). Cough strength may become diminished in older adults from age-related sarcopenia and changes in respiratory and physical functions (Kaneko et al., 2019). However, even older adults with preserved physical performance who presented with dysphagia exhibit cough and respiratory muscle strength (Kaneko et al., 2024). The combination of dysphagia, reduced cough, and respiratory muscle strength may increase the risk of aspiration pneumonia. Therefore, cough should be an important component of a dysphagia assessment.

For decades, SLPs have used limited knowledge of cough to largely guide decision making in dysphagia management. Dating back to 1983, clinicians were encouraged to instruct patients to cough as hard as possible to evaluate the apparent strength and quality of the cough (Logemann, 1983). Many clinicians and professionals continue to subjectively measure cough strength and relate it to the patient's ability to clear aspirated material. A recent study was conducted to determine if SLPs assessed cough during clinical swallow evaluations (Mir & Hegland, 2021). Findings from this study showed that 84.6% of participants subjectively measured cough and further support the need for continued research and training on cough strength and its relationship to dysphagia. When combined with assessment of voice changes, the presence of coughing or choking is sensitive to the identification of dysphagia, including aspiration (Hassan & Aboloyoun, 2014). However, subjective measurements lack validity and reliability. There is inconsistent agreement between subjective description and objective measures of cough strength and effectiveness (Laciuga et al., 2016). It is important to incorporate objective measurements to accurately identify a patient's cough strength.

Cough Peak Flow. Cough peak flow (CPF) measures the maximum expiratory flow during the compression phase of the cough after rapid glottic opening occurs (Brennan et al., 2022). The gold standard for measuring cough peak flow is with a pneumotachograph that is commonly used in research laboratories. However, this is not easily accessible or affordable to practicing clinicians in hospitals or clinics. Portable peak flow meters are available that are compact and cost-effective. A cough peak flow meter is a device used to measure cough strength. During this assessment the peak flow meter is placed at the patient's mouth, and they are instructed to breathe deeply and produce the strongest cough possible. This handheld cough testing tool has been found to be accurate in measuring cough strength and dysphagia screening (Curtis & Troche, 2020; Sancho et al., 2004). A cough peak flow value above 160 L/min is required for an effective cough and less than 270 L/min is associated with risk of infection (Brennan et al., 2022). Lower cough peak flow values and cough measures were present in individuals with aspiration (Lee et al., 2023; Plowman et al., 2016; Sakai et al., 2020). A cough peak flow value less than 240 L/min was considered the cutoff value for identifying patients with dysphagia who were at risk for aspiration pneumonia (Bianchi et al., 2012). Patients with pneumonia are more likely to have dysphagia and lower peak cough values, suggesting these two variables to be risk factors for pulmonary complications (Choi et al., 2021).

Current research has shown evidence supporting the relationship between cough strength and dysphagia. Objective measurements of voluntary cough strength have been studied in various patient populations and in conjunction with multiple assessment tools. Individuals with Parkinson's disease were found to have increased variability of cough effectiveness due to sensorimotor changes in the peripheral and central nervous system compared to healthy older adults (Borders et al., 2021). Lower cough peak flow measurements were significantly associated with aspiration during a modified barium swallow study in males with Parkinson's disease (Lee et al., 2023). Cough peak flow measurements have also been studied in other neurological populations, such as those who have experienced a stroke. Lower peak flow measurements increased the risk of aspiration in patients with ischemic stroke (Min et al., 2018). Patients may lack the ability to protect their airway following a stroke. When prolonged dependency on mechanical ventilation is needed, a tracheostomy is performed to support ventilator weaning and respiratory support. Cough function has also been found to be significantly improved following tracheostomy decannulation in stroke patients (Park & Lee, 2018). There are few studies on cough peak flow in individuals with COPD (Brennan et al., 2022). However, one study found lower cough peak flow values were present in males with severe COPD and frequent exacerbation, consisting of worsening symptoms (Batrawy & Elassal, 2014).

Instrumental Assessment of Cough and Swallowing. Cough function and its relationship to instrumental swallow assessments has also been studied. Voluntary cough flow values were significantly associated with the proportion of aspiration expelled during a FEES study in patients with neurodegenerative diseases (Borders et al., 2022). Higher values of peak expiratory flow rate were associated with an increased ability to remove material from the glottis. This study also accounted for the depth of aspiration, indicating that both cough strength and depth of aspiration can influence airway clearance efficiency. Smaller bolus volume and more superior aspiration locations may require lower cough airflow (Borders et al., 2022). The viscosity of trials also plays a role during instrumental assessments. There was a significant association between cough response to aspiration and viscosity of trials during an instrumental swallow assessment (Miles et al., 2018). Thinner liquids were more likely to elicit a cough reflex compared to thicker consistencies. Aspiration and a cough response were more likely to occur with large volumes of thin liquids than smaller volumes. This indicates that cough response may be a threshold-dependent response based on the amount aspirated.

The utilization of cough peak flow values has been studied during instrumental swallow assessments, specifically modified barium swallow studies to better understand its role in dysphagia management. Higher PAS scores from a modified barium swallow study were found to be related to lower peak cough flows and dysphagia severity (Lee et al., 2023; Silverman et al., 2015). These studies support the use of cough peak flow measurements in instrumental swallow studies. This comprehensive approach can improve interventions to reduce respiratory morbidity and overall patient prognosis.

Purpose of the Study

Adequate airway protection requires precise control of swallowing and cough function. A strong, effective cough is necessary for individuals with dysphagia to defend their airway from foreign material. There are many recent studies investigating cough function in specific populations. However, evidence is lacking in the relationship between cough and swallow function in patients with COPD in the acute care population. Many speech pathologists have expressed interest in incorporating cough measurement in their dysphagia practice (Mir & Hegland 2021). Evaluating the relationship between cough strength and swallow function is crucial, as both are key airway protective mechanisms. Identifying those with weak cough strength can aid in early detection of dysphagia, guide clinical interventions, and help prevent complications such as aspiration pneumonia. Objective cough strength assessment could be easily implemented in a dysphagia evaluation. This study will provide critical information for medically based speech pathologists and can ultimately reduce hospital readmissions, improve patient safety, and enhance quality of life. The first goal of this study is to determine if there is a relationship between lower peak cough flow values and participants with COPD. The cut-off value for this study will be a peak flow value of 240 L/min or less. This cut-off value was selected as a previous study found that a cough peak flow less than 240 L/min was indicative of an increased aspiration risk in patients with dysphagia (Bianchi et al., 2012). The second goal of this study is to examine the use of the PAS during a modified barium swallow study in participants with COPD. Lastly, the third goal is to examine the relationship between PAS scores and peak cough flow values in participants. This study will be conducted to address the following research questions:

(1) Do individuals with COPD demonstrate cough peak flow values less than or equal to 240 L/min?

(2) Do individuals with COPD demonstrate PAS scores higher than 2 during a modified barium swallow study?

(3) Is there a significant relationship between cough peak flow values and PAS scores?

Based on these questions, the following hypothesis were developed:

(1) Individuals with COPD will demonstrate cough peak flow values less than or equal to 240 L/min.

(2) Individuals with COPD will demonstrate PAS scores higher than 2 during a modified barium swallow study.

(3) There will be a significant relationship between cough peak flow values and PAS scores.

These outcomes were determined as evidenced by previous studies and current literature on dysphagia and COPD. There is emerging evidence on respiratory function and its relationship with aspiration risk and airway safety during eating and drinking. A previous study determined a cough peak flow value less than or equal to 240 L/min was indicative of worsening aspiration risk during a modified barium swallow study in patients with dysphagia (Bianchi et al., 2012). Therefore, it is hypothesized that the participants in this study will have similar cough peak flow values. Secondly, it is hypothesized that participants will demonstrate PAS scores higher than 2. A score higher than 2 is indicative of airway compromise. Based on current research, respiratory impairments can lead to impaired respiratory and swallow coordination, and therefore, will have higher occurrences of penetration and aspiration. Therefore, the participants in this study will experience higher PAS scores given their respiratory diagnosis and presence of dysphagia. Lastly, there will be a significant relationship between PAS scores and cough peak flow values. The PAS score is based on the patient's response. For example, a PAS score of 2 means that the participant was able to eject material that entered the airway. An efficient cough would be the most reasonable method for a participant to eject material from their airway. Therefore, the two values will likely share a significant relationship.

Chapter III

Method

Participants

Approval from the Valdosta State University Institutional Review Board (Appendix A), as well as permission from Tift Regional Medical Center (Appendix B), was obtained prior to the initiation of participant enrollment. Patient consent was obtained from all participants (Appendix C). Purposive sampling was used for this study. Participants in this study included a minimum of 10 hospitalized patients with a diagnosis of COPD. A diagnosis of COPD was confirmed by a thorough medical chart review of the participant's active diagnoses listed. This study included male and female individuals ranging from 40 to 80 years old. Candidates were referred to the speech pathologist by a physician for a dysphagia evaluation. Inclusion criteria included the ability to follow simple commands and sustain an adequate level of alertness to participate. Exclusion criteria included the presence of a tracheostomy, recent neck surgery, Parkinson's disease, and/or acute stroke. These impairments are excluded as there is already sufficient evidence supporting their relationship with impaired cough function. This study was conducted in a rural, acute care hospital that contained 172 patient rooms and included a variety of units, e.g., the intensive care unit, orthopedic unit, and general medical surgery unit.

Procedures

Modified Barium Swallow Study. The presence, depth, response to penetration or aspiration, and result of compensatory strategies can be examined during the modified barium swallow study. For this study, participants underwent an MBSS to further evaluate swallow function and response to aspiration, if present. All participants were positioned in an upright, seated position. The participants were positioned in a lateral view to visualize the oral cavity, pharyngeal cavity, larynx, and cervical esophagus. The speech pathologist administered multiple trials with various viscosities. Thin liquid barium via teaspoon, thin liquid via cup edge, and/or sequential swallows of thin liquid barium were first administered. Nectar-thick barium was also considered depending on the patient's performance and clinical judgement. Following the thin barium trials, pureed barium consistency and a portion of graham cracker coated in barium were administered. Pureed and solid boluses were administered only if the patient demonstrates adequate airway protection and pharyngeal clearance during the liquid boluses.

Penetration-Aspiration Scale. The PAS was used to identify the severity and presence of dysphagia during the MBSS and was included in the patient's MBSS results. The PAS is a validated measure used to calculate the extent of laryngeal penetration and/or aspiration during the swallow (Brooks et al., 2019). It is an 8-point interval scale used to categorize the patient's overall penetration or aspiration events (Rosenbek et al., 1996). A PAS score of 1-2 indicates a normal swallow function, while a score of 3 or higher indicates abnormal swallow function. The PAS score is based on the highest score observed across all swallowing trials during the MBSS. The score reflects the greatest level of airway invasion, and the patient's ability to eject material from the airway, which is an important consideration when measuring cough strength. An effective cough could be essential in ejecting aspirated material.

Cough Peak Flow Meter. The cough peak flow meter has a high sensitivity and specificity as an indicator of aspiration when restarting food intake (Sakai et al., 2020). This handheld tool was found to be a valid tool for cough assessment and dysphagia screening (Curtis

& Troche, 2020). Prior to the participant's MBSS, voluntary cough strength was obtained by using a peak flow meter. The participants were instructed to breathe deeply and produce the strongest cough possible. Three cough measurements were obtained with the average value recorded as the peak flow value for data analysis. The data collection table is located in Appendix D.

Design

A correlational research design was used to measure the relationship between cough strength and level of aspiration. Correlational research is often used in healthcare research since it can be used in studies with independent variables that are unable to be manipulated (Curtis et al., 2016). Voluntary cough peak flow values were obtained prior to the dysphagia evaluation. Cough peak flow rates were recorded by the primary speech language pathologist (SLP). Following cough peak flow assessments, the modified barium swallow study was performed by the primary SLP. The PAS score was obtained following the modified barium swallow study results. An additional SLP also completed the PAS to obtain inter-observer agreement. The additional SLP separately viewed the modified barium swallow studies and provided a PAS score for each patient. The scores were then compared to the primary SLP's findings. Any discrepancies between the scores were discussed with the results of an agreed score by both SLPs. Demographic information such as age, sex, reason for admission, and significant past medical history was recorded.

Statistical Analysis

Spearman's *rho* coefficient was used to analyze the association between peak flow values and PAS scores. A scatterplot was used to display the relationship between the variables. An alpha level of $p < 0.05$ was used to determine statistical significance.

Chapter IV

Findings

The purpose of this study was to investigate the relationship between cough strength and swallow function in patients with COPD. Average cough peak flow values were calculated from three separate scores. The PAS scores were determined by choosing the best score to summarize the patient's overall swallow function. A Spearman's correlation was calculated to determine the relationship between cough peak flow rate and PAS score.

Ten participants were assessed using cough peak flow measurements and the PAS. All participants from this study demonstrated average cough peak flow rates of less than 240 L/min (see Table 3). Interrater reliability was obtained when scoring the PAS scores. There were no discrepancies and both raters assigned the exact same number for each participant. Findings revealed that lower cough peak flow rates were associated with worse PAS scores, indicating a higher risk of airway invasion. Spearman's *rho* coefficient was conducted to examine the relationship between age, gender, average cough peak flow, and PAS scores. There was no significant correlation between age and average cough peak flow (rs = -.122, p = .738). Similarly, age was not significantly correlated with PAS scores (rs = .495, p = .146). Gender was not significantly associated with PAS scores (rs = -.076, p = .834). However, there was a statistically strong negative correlation between average cough peak flow and PAS scores (rs = -.761, p = .011). This indicates that lower cough peak flow was associated with higher PAS scores, supporting this study's hypothesis (see Figure 3). These results suggest that cough strength may be a valuable clinical marker for identifying dysphagia risk in patients with COPD.

Table 3

Participant Cough Peak Flow Rates and PAS Scores.

Participant	CPF 1	CPF 2	CPF 3	Average CPF	PAS Score
1	200	200	250	216.67	1
2	100	150	150	133.33	2
3	150	150	155	151.67	2
4	150	153	153	152	1
5	100	120	100	106.67	3
6	60	60	60	60	7
7	200	200	160	173.33	1
8	60	60	60	60	3
9	100	100	110	103.33	1
10	200	210	210	206.67	1

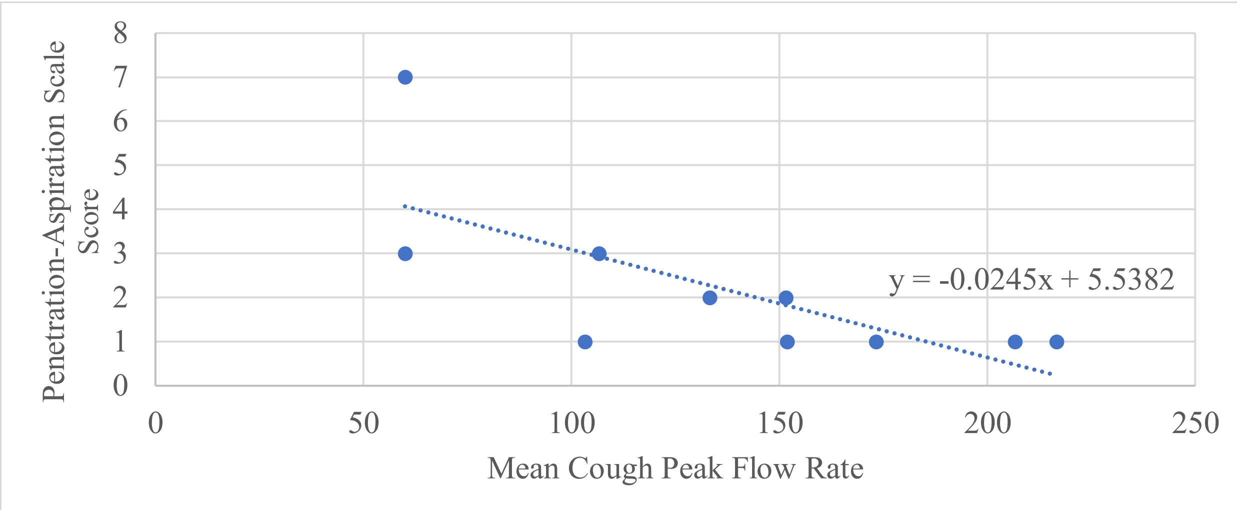
Table 4

Participant's Age and Gender

Participant	Age	Gender
1	64	Male
2	68	Female
3	70	Male
4	59	Female
5	80	Male
6	66	Male
7	62	Male
8	67	Female
9	63	Female
10	77	Male

Figure 3

Mean Cough Peak Flow Rates and PAS Scores



Chapter V

Discussion

The purpose of this study was to investigate the relationship between cough strength and swallow function in patients with COPD. This study recruited hospitalized patients who experienced difficulty swallowing. All patients participated in a modified barium swallow study to further assess swallow function and the occurrence of aspiration. The PAS was used to classify the overall depth of penetrated or aspirated intake and the participants' response to airway invasion. Cough strength was measured using a peak flow meter. The average voluntary cough strength and PAS scores were then analyzed to determine if there was a significant relationship between the variables.

Three hypotheses were proposed for this study. First, it was hypothesized that participants would demonstrate cough peak flow rates less than or equal to 240 L/min. Results supported this hypothesis, as all the participants demonstrated average cough peak flow rates below this threshold. These findings suggest that the presence of COPD and dysphagia may contribute to reduced cough strength. This study's findings of low cough peak flow rates (less than 240 L/min) are consistent with previous studies (Bianchi et al., 2012). Airway inflammation and obstruction associated with COPD likely decrease the forced expiratory volume, thereby impairing cough strength (Agarwal et al., 2023). This reduction in forced expiratory volume can lead to low cough peak flow rates. Low cough peak flow rates can increase the risk of infection and pulmonary complications (Brennan et al., 2022; Choi et al., 2021).

The second hypothesis predicted that participants would demonstrate PAS scores higher than 2 during a modified barium swallow study. This was not widely observed. Only three participants experienced airway compromise during their swallow study (PAS score >2). The majority demonstrated adequate swallow function with the ability to protect their airway from aspiration. Therefore, the presence of COPD may to some degree impact swallow function but did not appear to compromise airway safety by aspiration. This small number of participants with airway compromise could be that these patients were not experiencing exacerbation of COPD symptoms at the time of assessment. COPD exacerbation symptoms include sudden worsening of respiratory symptoms such as dyspnea, frequent coughing, wheezing, and fatigue. A previous study found that patients admitted with COPD exacerbation exhibited a significant correlation between lung function and self-reported dysphagia (Lindh et al., 2021).

Lastly, this author hypothesized that there would be a significant relationship between cough peak flow values and PAS scores. Lower cough peak flow rates were significantly associated with worse PAS scores. Lower cough peak flow rates could be secondary to reduced expiratory volume as previously stated. However, the presence of age-related sarcopenia and deconditioning could also play a role. Reduced muscle mass and strength can impair physical performance and contribute to functional decline (Köller, 2023; Watson, 2014). Sarcopenic dysphagia can contribute reduced tongue strength and cough peak flow rates when compared to non-sarcopenic patients (Maeda & Akagi, 2017). Findings supported the relationship between the two variables, highlighting cough strength as a potential clinical indicator for identifying dysphagia risk in individuals with COPD.

Of the ten participants recruited with COPD, six were male and four were female (see Table 4). The majority of participants were in their 60s, indicating that this age range may be a peak period for the onset of dysphagia symptoms. Participants with higher cough peak flow rates demonstrated more efficient swallow function and lower PAS scores. Participants 6 and 8 both demonstrated significantly low cough peak flow rates (60 L/min). However, participant 6 performed much worse on his swallow study, demonstrating significant aspiration. Although both were of similar age, they differed in gender and functional status. Participant 6, who was severely debilitated, required total assistance with tasks such as eating and bathing. This participant also required supplemental oxygen via nasal cannula. In contrast, participant 8 was fully independent with daily tasks and did not require supplemental oxygen. This comparison suggests that poor physical health and deconditioning may contribute to impaired swallow function. Future studies could investigate the relationship between participants' physical strength as a factor influencing reduced CPF rates and dysphagia severity.

Clinical Implications

The findings from this study offer valuable insights into early identification of dysphagia risk among individuals with COPD. Specifically, lower cough peak flow rates were significantly associated with higher PAS scores, suggesting that reduced cough strength may serve as a clinically relevant indicator of reduced airway protection during swallowing. All participants in this study demonstrated CPF rates below 240 L/min; a value linked to aspiration risk from previous studies (Bianchi et al., 2012). Although only three participants exhibited PAS scores greater than 2, these findings further support the relationship between diminished cough strength and aspiration risk. The consistency of low cough peak flow values across participants reinforces the utility of cough peak flow as a non-invasive and accessible screening measure in evaluating patients with COPD.

Most participants were in their 60s, aligning with literature that indicates increased dysphagia risk occurs with advancing age. Other factors may also play a role in dysphagia, including sarcopenia and the presence of neuromuscular conditions. This study's findings suggest that this age group may represent a critical window for early detection of dysphagia, especially those with respiratory conditions that compromise cough function. Incorporating cough peak flow assessments into routine dysphagia evaluations may help identify individuals who would benefit from interventions, including dysphagia therapy and respiratory muscle strength training. Early detection of at-risk individuals could facilitate timely intervention and reduce the risk of aspiration-related complications such as pneumonia.

Limitations

There were several limiting factors for this study that should be acknowledged. First, the small sample size limited the ability to generalize results to other groups. A small sample size may not adequately represent the broader population of individuals with COPD. The few number of participants with high PAS scores (>2) restricts generalizability to those with more severe swallowing impairments. Additionally, this study was conducted in a single clinical setting and primary focuses on individuals in their 60's, hindering generalizability to other age ranges and settings. This may not capture the full spectrum of individuals with COPD and dysphagia.

This study only utilized the use of the cough peak flow meter as the sole measurement of cough strength. Cough peak flow rates were measured using a cost-effective handheld device. This handheld device is commonly utilized in clinical settings particularly by pulmonary rehabilitation departments and by respiratory therapists. Although it is standard practice for SLPs to utilize this device into dysphagia evaluations, there is emerging evidence supporting its use in determining airway protection. Future studies could analyze differences among various spirometers to determine validity and consistency of equipment. Reliability of this study was also threatened as only one SLP conducted the cough peak flow assessments. Future studies should have more than one clinician measure the cough peak flow values to establish interrater reliability.

Recommendations

Despite several limitations previously mentioned, this study provides a foundation for future research and the clinical application of measuring cough strength. Future studies should consider the limitations of this current study. First, a larger sample size would improve generalization of results to all individuals with COPD. This sample consisted of a majority of participants in the same age range. Future studies could include a more diverse sample to enhance external validity. Since COPD can be broken down into stages, this should also be considered and further analyzed in future studies. Knowing which stage of COPD indicates the highest risk for dysphagia and aspiration could provide critical information to providers for early diagnosis and intervention. Another recommendation for future studies includes analyzing participants' physical health and their relationship to cough strength. As previously discussed, participants 6 and 8 both demonstrated weak cough peak flow rates but the participant with better physical health had higher cough strength. Investigating other cough-related measures, e.g., reflexive cough strength may also provide a more comprehensive understanding of airway protection mechanisms. Nonetheless, the findings of this study supported the utilization of cough peak flow measurements in dysphagia management. Therefore, clinicians should consider implementing these measurements into their assessments and decision making for effective determination of airway protection in patients with dysphagia, especially those with compromised respiratory function.

Chapter VI

Conclusion

Emerging evidence has indicated a significant association between dysphagia and COPD. Individuals with COPD may experience impaired respiratory swallow coordination as a result of increased respiratory rate and impaired swallow patterns. Coughing is often a common symptom associated with dysphagia. In conclusion, this study demonstrated that there is a significant relationship between cough strength and swallow function in patients with COPD. All participants had an average cough peak flow rate less than 240 L/min, indicating reduced cough peak flow strength as evidenced by previous studies. The findings suggest that lower cough peak flow rates are associated with an increased risk of aspiration, as demonstrated by higher PAS scores. The results emphasize the importance of including cough strength assessments into dysphagia evaluations for patients with COPD. While this study was limited by a small sample size, the results provide clinically relevant insights into the relationship between respiratory and swallow function for this population. Future research should focus on larger sample sizes and settings to expand the generalizability of findings. Future research should also include intervention studies to examine the efficacy of treatment strategies in improving cough strength and reducing aspiration risk.

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Appendix A:

IRB Approval

Institutional Review Board (IRB)
for the Protection of Human Research Participants

EXPEDITED PROTOCOL APPROVAL REPORT

Protocol Number: 04530-2024 **Responsible Researcher:** Rebekah F. Cottle

Supervising Faculty: Dr. Mary Gorham-Rowan **Co-Investigator:** n/a

Project Title: *The Relationship Between Cough Peak Flow Values and Dysphagia in the Acute Care Population.*

Level of Risk: ☒ Minimal ☐ More than Minimal

Type of Review: ☒ Expedited ☐ Convened (Full Board)

Approval Categories: 4 & 5

Approval Date: 08.21.2024

Expiration Date: 08.21.2027

Consent Requirements:

- ☒ **Adult Participants – Written informed consent with documentation (signature)**
- ☐ Adult Participants – Written informed consent with waiver of documentation (signature)
- ☐ Adult Participants – Verbal informed consent (Research Statement)
- ☐ Adult Participants – Waiver of informed consent
- ☐ Minor Participants – Written parent/guardian permission with documentation (signature)
- ☐ Minor Participants – Written parent/guardian permission with waiver of documentation (signature)
- ☐ Minor Participants – Verbal parent/guardian permission
- ☐ Minor Participants – Waiver of parent/guardian permission
- ☐ Minor Participants – Written assent with documentation (signature)
- ☐ Minor Participants – Written assent with waiver of documentation (signature)
- ☐ Minor Participants – Verbal assent
- ☐ Minor Participants – Waiver of assent
- ☐ Waiver of some elements of consent/permission/assent

Comments:

Approval:
This research protocol is ***approved****. Your approved consent form, bearing the IRB approval stamp and protocol expiration date is attached. If you prefer the original stamped consent, please email tmwright@valdosta.edu and the form will be sent via inter-office mail, or you may come by the OSPRA office to obtain the original.*

Elizabeth Ann Olphie 08.21.2024

Elizabeth Ann Olphie, IRB Administrator Date

Form Revised: 07.09.2024 - tw

ADDITIONAL INFORMATION FOR RESEARCHERS:

If your protocol received expedited approval, it was reviewed by a two-member team, or, in extraordinary circumstances, the IRB Administrator, the Chair, or Vice-Chair of the IRB. Although the expediters may approve protocols, they are required by federal regulation to report expedited approvals at the next IRB meeting. At that time, other IRB members may express any concerns and may occasionally request minor modifications to the protocol. In rare instances, the IRB may request that research activities involving participants be halted until such modifications are implemented. Should this situation arise, you will receive an explanatory communiqué from the IRB.

Protocol approvals are valid for three years unless otherwise noted. In rare instances, when a protocol is determined to place participants at more than minimal risk, the IRB may shorten the approval period so that protocols are reviewed more frequently, allowing the IRB to reassess the potential risks and benefits to participants. The expiration date of your protocol approval is noted on the approval form. You will be contacted no less than one month before this expiration date and will be asked to either submit a final report if the research is concluded or to apply for a continuation of approval. It is your responsibility to submit a continuation request in sufficient time for IRB review before the expiration date. If you do not secure a protocol approval extension prior to the expiration date, you must stop all activities involving participants (including interaction, intervention, data collection, and data analysis) until approval is reinstated.

Please be reminded that you are required to seek approval of the IRB before amending or altering the scope of the project or the research protocol or implementing changes in the approved consent process/forms. You are also required to report to the IRB, through the Office of Sponsored Programs & Research Administration, any unanticipated problems or adverse events that become apparent during the course or as a result of the research and the actions you have taken.

Please refer to the IRB website (https://www.valdosta.edu/academics/graduate-school/research/office-of-sponsored-programs-research-administration/institutional-review-board-irb-for-the-protection-of-human-research-participants.php) for additional information about Valdosta State University's human protection program and your responsibilities as a researcher.

Form Revised: 07.09.2024 - tw

Appendix B:

Letter of Approval

SOUTHWELL

Christopher K. Dorman
President & Chief Executive Officer

901 East 18th Street
Tifton, Georgia 31794
229-382-7120

MySouthwell.com

July 25, 2024

Valdosta State University
1500 North Patterson Street
Valdosta, GA 31698

To Whom This May Concern:

Please allow this letter to serve as notice that upon the approval of and pursuant to the conditions of such approval by Valdosta State University's Institutional Review Board and Tift Regional Medical Center's ("TRMC") research review committee, TRMC will permit Rebekah Cottle to conduct her study, The Relationship Between Cough Peak Flow Values and Dysphagia in the Acute Care Population, through testing and research at Tift Regional Medical Center.

Sincerely,

Christopher K. Dorman

Christopher K. Dorman
President & Chief Executive Officer

TIFT REGIONAL MEDICAL CENTER • SOUTHWELL MEDICAL • SOUTHWELL HEALTH AND REHABILITATION • PHYSICIAN PRACTICES

Appendix C:

Patient Consent Form

VALDOSTA STATE UNIVERSITY
Consent to Participate in Research

You are being asked to participate in a research project entitled "The Relationship Between Cough Peak Flow Values and Dysphagia in the Acute Care Population." This research project is being conducted by Rebekah Cottle, a student in Communication Science and Disorders at Valdosta State University. The purpose of this research is to determine the relationship between cough strength and swallow function in individuals with Chronic Obstructive Pulmonary Disease. Your participation is entirely voluntary.

As described in more detail below, we will ask you to participate in measuring cough strength. We will also ask you to participate in a modified barium swallow study for further assessment of your swallow function. Someone in your position might be interested in participating because it will help us learn more about the relationship between cough strength and swallow difficulty. Because there are some risks, such as aspiration of contents, you may not wish to participate. It is important for you to know that you can stop your participation at any time. More information about all aspects of this study is provided below.

This form includes detailed information to help you decide whether to participate in this study. Please read it carefully and ask any questions that you have before you agree to participate. Please be sure to retain a copy of this form for your records.

Procedures: Your participation will involve two separate tasks. The first task involves participating in cough strength. You will be asked to cough into a single use mouthpiece that measures the peak flow of your cough. You will be asked to do this three times, with your average score being used for data analysis. The second task involves a swallowing study. A swallowing study is regularly performed in the acute hospital setting. You will be given various textures to swallow while viewing your swallow function under fluoroscopy. This project is expected to take 30 minutes to 45 minutes to complete. If you agree to participate, the researchers will also collect your past medical history from your electronic medical record.

There are no alternatives to the experimental procedures in this study. The only alternative is to choose not to participate at all.

Possible Risks or Discomfort: This is a minimal risk research study. That means that the risks of participating are no more likely or serious than those you encounter in everyday activities. Minor risks that may occur during the swallow study include coughing and difficulty swallowing. Although there are no known risks associated with these research procedures, it is not always possible to identify all potential risks of participating in a research study. However, the University has taken responsible safeguards to minimize potential but unknown risks.

By agreeing to participate in this research project, you are not waiving any rights that you may have against Valdosta State University for injury resulting from negligence of the University or its researchers.

Potential Benefits: Although you will not benefit directly from this research, your participation will help the researcher gain additional understanding of the relationship between cough strength and swallow function in individuals with COPD. Knowledge gained may contribute to addressing future research and interventions to improve quality of life in individuals with this condition.

Participant's Initials: ________

Costs and Compensation: There are no costs to you and there is no compensation (no money, gifts, or services) for your participation in this research project.

Assurance of Confidentiality: Valdosta State University and the researcher will keep your information confidential to the extent allowed by law. Members of the Institutional Review Board (IRB), a university committee charged with reviewing research to ensure the rights and welfare of research participants, may be given access to your confidential information.

Your information will be kept confidential and be protected throughout this study. Your results from the cough measurements and swallow study will be recorded in a basic table design. Your name or other identifying information will not be collected. The results from the swallow study will be reported in your electronic medical record, as it would be even if you were not participating in this study. Your information will only be accessed by the primary researcher, and collected data will be stored in a locked designation throughout this study. The information will be kept throughout the entirety of the study but will be shredded 3 years after the study is completed. Data from this study will be reported without participant name and should not be identifiable. Data from this study will be reported in combination with results obtained from other participants.

Voluntary Participation: Your decision to participate in this research project is entirely voluntary. If you agree now to participate and change your mind later, you are free to leave the study. Your decision not to participate at all or to stop participating at any time in the future will not have any effect on any rights you have or any services you are otherwise entitled to from Valdosta State University. Should you decide to withdraw from the study after data collection is complete, your information will be deleted and not included in the research results.

Information Contacts: Questions regarding the purpose or procedures of the research should be directed to Rebekah Cottle at rfoster@valdosta.edu. This study has been approved by the Valdosta State University Institutional Review Board (IRB) for the Protection of Human Research Participants. The IRB, a university committee established by Federal law, is responsible for protecting the rights and welfare of research participants. If you have concerns or questions about your rights as a research participant, you may contact the IRB Administrator at 229-253-2947 or irb@valdosta.edu.

Agreement to Participate: The research project and my role in it have been explained to me, and my questions have been answered to my satisfaction. I agree to participate in this study. By signing this form, I am indicating that I am 18 years of age or older. I have received a copy of this consent form.

I would like to receive a copy of the results of this study: _____ Yes _____ No

Mailing Address: ____

E-mail Address: ______________________

____
Printed Name of Participant

____
Signature of Participant Date

____
Signature of Person Obtaining Consent Date

This research project has been approved by the Valdosta State University Institutional Review Board for the Protection of Human Research Participants through the date noted below:

VALDOSTA STATE UNIVERSITY INSTITUTIONAL REVIEW BOARD
APPROVAL DATE 08.21.2024
IRB # 04530-2024
EXPIRATION DATE 08.21.2027

Appendix D:

Data Collection Table

PARTICIPANT	PAST MEDICAL HISTORY/ADDITIONAL INFORMATION	CPF VALUE 1	CPF VALUE 2	CPF VALUE 3	CPF AVG VALUE	PENETRATION-ASPIRATION SCALE SCORE
1	64-year-old male Reduced mastication, adequate pharyngeal function	200	200	250	216.67	1
2	68-year-old female Significant dysphagia, supplemental O2	100	150	150	133.33	2
3	70-year-old male Significant dysphagia, vallecular residue	150	150	155	151.67	2
4	59-year-old female Reduced esophageal motility	150	153	153	152	1
5	80-year-old male Supplemental O2, osteophytes, reduced pharyngeal constriction, heart failure	100	120	100	106.67	3
6	66-year-old male Aspiration, pneumonia Hx tobacco use Supplemental O2, Physically debilitated	60	60	60	60	7
7	62-year-old male Reduced esophageal motility	200	200	160	173.33	1
8	67-year-old female Hx tobacco use, independent with tasks	60	60	60	60	3
9	63-year-old female Esophageal spasms	100	100	110	103.33	1
10	77-year-old female Supplemental O2 Reduced esophageal motility	200	210	210	206.67	1