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Laryngeal sensory testing using flexible endoscopy

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Dissertation

LARYNGEAL SENSORY TESTING USING FLEXIBLE ENDOSCOPY

by

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ABSTRACT

Sensory input from the laryngeal mucosa is vital for triggering protective airway reflexes. The laryngeal adductor reflex (LAR) is a brief vocal fold adductor reflex in response to stimulation of the laryngeal mucosa. Depressed LAR may lead to aspiration of foreign substances into the airway. Loss of laryngeal sensation has thus been considered as one of the risk factors associated with aspiration and airway complications in patients with dysphagia.

Laryngeal sensation can be endoscopically tested by lightly and briefly touching a patient's arytenoids or epiglottis with the tip of a flexible laryngoscope (the touch method). In a preliminary study, we endoscopically investigated the laryngeal sensation and swallowing ability of healthy adults and patients with dysphagia. The results indicated an association between sensory deficits as determined by the touch method and penetration/aspiration of trial boluses in both healthy adults and patients with dysphagia. However, the pressure applied to the larynx using this touch method might not be consistent, and the expected responses elicited by this method were uncertain.

Study 1 of this dissertation investigated the variability in the pressure delivered by clinicians using the touch method. The study also reported on the types of various subject

responses to the touches. The results revealed that there was a wide range of pressure levels exerted by examiners. This suggested the need for further research to establish the validity of this diagnostic tool. The study also showed that the LAR always occurred in response to touch in normal volunteers, suggesting that this technique may be quite sensitive at detecting sensory deficits in a person who does not exhibit an LAR in response to touch.

Study 2 examined hospitalized patients with symptoms of dysphagia. The question of interest was whether an absent LAR in response to touch was associated with aspiration or pneumonia. No significant association was found between absent LAR and aspiration of food or liquid; however, a significant association was observed between absent LAR and the occurrence of pneumonia. The study indicated that the touch method has potential for predicting pneumonia in patients with swallowing problems.

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LIST OF ABBREVIATIONS

FEES	Fiberoptic Endoscopic Evaluation of Swallowing
iSLN	The internal branch of superior laryngeal nerve
LAR.....	The laryngeal adductor reflex
PAS	Penetration-Aspiration Scale

1. DISSERTATION INTRODUCTION

Sensory input is vital to the oral, pharyngeal, and esophageal phases of swallowing. The afferent input arising from the laryngeal area is particularly important in triggering various reflexes, which protect the respiratory tract against the invasion of foreign materials. Loss of laryngeal sensation depresses those airway protective reflexes. Thus, many have considered patients with sensory deficits to be more likely to aspirate and therefore at higher risk for aspiration pneumonia. Nevertheless, methods for laryngeal sensory testing are not well established. Therefore, a series of studies included in this dissertation was conducted in order to assess the clinical utility of laryngeal sensory testing in swallowing evaluation.

This introduction outlines the rationale leading to the purpose of the two studies in this dissertation: firstly, a literature synthesis establishes the foundation of the work, introducing two methods of laryngeal sensory testing described in previous literature. Secondly, the preliminary study in which we compared the two methods of laryngeal sensory testing is described. Finally, the aims of this dissertation are presented.

1.1 Laryngeal sensation and airway protective mechanism

The afferent innervation of the human larynx is supplied by the internal branch of the superior laryngeal nerve (iSLN). The iSLN splits into superior, middle, and inferior branches in humans. The superior branch provides sensory innervation mainly to the surface of the epiglottis, while the middle innervates the mucosa of the aryepiglottic fold, the true and false vocal folds, the laryngeal ventricle, and the mucosa covering the

arytenoid cartilage. The inferior ramus distributes several branches to the posterior aryepiglottic fold, the mucosa covering the arytenoid cartilage, and the interarytenoid space, extending to the subglottic mucosa at this site (Jafari, Prince, Kim, & Paydarfar, 2003; Sulica, 2004).

The iSLN and its fibers extend their endings in the epithelia of the laryngeal mucosa. These endings have been histologically classified into five different types of specialized receptors: pressure receptors, drive receptors, thermal receptors, irritant receptors, and C-fiber endings (Sant'Ambrogio & Widdicombe, 2001; Widdicombe, 2001). In the human larynx, the sensory receptors are densely populated in the laryngeal surface of the epiglottis (Villaverde, Pastor, Calvo, Ferran, & Sprekelsen, 1994), the aryepiglottic fold (Yoshida, Tanaka, Hirano, & Nakashima, 2000), and supraglottic mucosa near the arytenoid cartilages (Ruoppolo et al., 2015; Sampson & Eyzaguirre, 1964).

The majority of the cell bodies of the superior laryngeal nerve are located in the nodose ganglion (Sulica, 2004). These afferents ascend and synapse directly with the *nucleus tractus solitarius* in the medulla (Kidder, 1995). The afferent fibers then project to the efferent component, the *nucleus ambiguus* via interneurons (Bolser, Pitts, Davenport, & Morris, 2015). The motor neurons within the *nucleus ambiguus* then travel to the recurrent laryngeal nerve, activating the laryngeal muscles. The activation of this reflexive pathway triggers the laryngeal adductor reflex (LAR), which is seen as a brief adduction of the vocal folds, lasting approximately 0.5s in humans (Domer, Kuhn, & Belafsky, 2013; Shock et al., 2015). Mechanical or chemical stimulation of the laryngeal

mucosa in the iSLN territory triggers the LAR (Andreatta, Mann, Poletto, & Ludlow, 2002; Dua, Surapaneni, Kuribayashi, Hafeezullah, & Shaker, 2011; Shingai & Shimada, 1976; Shock et al., 2015; Sun, Chum, Bautista, Pilowsky, & Berkowitz, 2011).

Additional reflexes include gag and cough reflexes as a level of protection of the airway when substances inadvertently enter the airway (Fukuda & Koga, 1997; Mazzone, Cole, Ando, Egan, & Farrell, 2011; Takatsuji et al., 2012; Widdicombe, 2001). Reduced laryngeal sensory function depresses the LAR (Andreatta et al., 2002) and other protective reflexes and may result in aspiration of foreign substances into the trachea and the lungs (Sasaki & Suzuki, 1976).

1.2 Laryngeal sensory deficits and swallowing function

Loss of laryngeal sensation is commonly found in patients with dysphagia (Aviv et al., 1996; Ku et al., 2010) and has thus been considered one of the risk factors associated with aspiration (Onofri, Cola, Berti, da Silva, & Dantas, 2014) and airway complications (Aviv et al., 2002). An endoscopic evaluation of swallowing has the capability of assessing laryngeal sensation. Two methods of laryngeal sensory testing have been used: the air pulse method and the touch method.

The air pulse method measures laryngeal sensory thresholds by using pressure- and duration-controlled air pulses generated by an air pulse stimulator (Aviv, Martin, Keen, Debell, & Blitzer, 1993). A puff of air is delivered through the working channel of a flexible laryngoscope to the mucosa overlying the arytenoid cartilages. At a certain pressure, the air puff should elicit the LAR. Laryngeal sensation can be quantified by

recording the pressure (mmHg) at which the LAR is triggered. A commercial air pulse stimulator (Pentax AP- 4000) can control the intensity of the air pulse stimulation ranging from 2mmHg to 10mmHg in pressure and 50ms in duration.

Based on the sensory thresholds found in healthy adults and the post-stroke dysphagia, laryngeal sensation has been defined as normal ($< 4\text{mmHg}$), moderate ($4\text{--}6\text{mmHg}$), and severe ($> 6\text{mmHg}$, (Aviv et al., 1996; Aviv et al., 1998). Laryngeal sensory deficits were also found in patients with chronic obstructive pulmonary disease (Clayton, Carnaby, Peters, & Ing, 2014) and post-radiation therapy for head and neck cancer (Parise Junior, Miguel, Gomes, Menon, & Hashiba, 2004).

However, there exists scant literature linking laryngeal sensory deficits with penetration/aspiration or other relevant clinical outcomes, so the clinical relevance of assessing laryngeal sensation remains unclear. A study performed on patients with dysphagia with heterogeneous medical diagnoses showed a strong association between sensory deficits and aspiration (Aviv et al., 2002), but another study with head and neck cancer patients who had undergone radiation therapy did not demonstrate a significant association (Ku et al., 2010). Accordingly, while the air pulse method allows clinicians and investigators to examine the reduction of sensation in the larynx, the true significance of these deficits has not been established.

An alternative to the air pulse method is a simple touch to the epiglottis (Langmore, Kenneth, & Olsen, 1988) or the arytenoids (Leow, Beckert, Anderson, & Huckabee, 2012) with the tip of a standard flexible laryngoscope. The clinician then

looks for signs that the patient sensed the touch. Such signs would be the LAR, a cough, a gag (Langmore et al., 1988), tearing, swallowing, or an examinee's report that he/she has felt the touch (L. P. Leow et al., 2012). If any of these signs is observed, laryngeal sensation is considered to be grossly intact, although the presence of these reactions cannot rule out minor sensory deficiencies (Langmore et al., 1988).

In clinical practice, the touch method has been more frequently used than the air pulse method because it requires only a flexible laryngoscope, which is readily available to clinicians. Nevertheless, literature regarding the touch method is extremely limited. Leow and colleagues conducted a cross-sectional study that compared laryngeal sensation of patients with Parkinson's disease who were free of swallowing problems with healthy adults using the touch method (L. P. Leow et al., 2012). Results revealed that individuals with Parkinson's disease did not have reduced sensation at the arytenoids compared to age-matched controls. Onofri and colleagues examined post-stroke patients with dysphagia using the touch method to determine the association between impaired sensation and penetration/aspiration (Onofri et al., 2014). In contrast to the study by Leow, this study found that in post-stroke patients, impaired sensation correlated highly with penetration and aspiration. This latter report suggests that testing laryngeal sensation with a gross touch may allow clinicians to identify patients who are at higher risk for aspiration. Sato and colleagues examined the association between sensory deficits and the occurrence of pneumonia in patients with dysphagia in a rehabilitation hospital (Sato et al., 2002). The authors asked the patients to verbally report when they felt the touch applied to the laryngeal surface of the epiglottis. Presence of the patient's report and the

swallowing reflex were taken as a sign of intact laryngeal sensation. The result revealed a significant link between reduced laryngeal sensation as determined by the touch method and the occurrence of pneumonia.

1.3 A preliminary study for the clinical utility of the touch method

We conducted a preliminary study to assess the ability of the air pulse method and the touch method to detect laryngeal sensory deficits, and to correlate recorded deficits with penetration/aspiration outcomes (Kaneoka, Krisciunas, Walsh, Raade, & Langmore, 2015). Participants received an endoscopic swallowing evaluation that included an assessment of sensation using the air pulse method, followed by the touch method. The results of the air pulse method were categorized as normal vs. impaired sensation, defined as the presence or absence of an LAR, and the results of the touch method were categorized as present vs. absent response. Penetration/aspiration was scored using the Penetration-Aspiration Scale (PAS; (Rosenbek, Robbins, Roecker, Coyle, & Wood, 1996b) and the results were dichotomized (abnormal (PAS score ≥ 3) /normal (PAS score < 3)). Four healthy and 10 adults with dysphagia completed the endoscopic swallowing evaluation, the air pulse method, and the touch method. The air pulse method identified laryngeal sensory impairments with greater frequency than the touch method ($S=19.0$, $p< 0.0001$). However, the impairment identified by the air pulse method was not associated with abnormal PAS scores ($p= 0.46$). On the other hand, the sensory deficits identified by the touch method were associated with abnormal PAS scores ($p= 0.05$). In conclusion, sensory impairment detected by the air pulse method did not appear to be associated with

penetration/aspiration, whereas significant laryngeal sensory loss revealed by the touch method was associated with penetration/aspiration. These findings directed this dissertation to further examine the capability of the touch method to predict the risk of aspiration and pneumonia in the individuals with dysphagia.

In the two studies included in this dissertation, the air pulse method was not utilized due to limitations of the commercial air-pulse stimulator. Hammer reported that the commercial device failed to deliver a stimulus on average in 17% of the trials and up to 25% of trials. The inconsistent stimulus delivery is likely to produce false negative responses (Hammer, 2009). This low reproducibility may also have been a source of reported poor inter-rater reliability (Cunningham, Halum, Butler, & Postma, 2007). In order to address the limitations of the commercial air pulse generator, Hammer developed a new laryngeal sensory stimulus delivery device. The stimulator consistently produced airbursts with a broader dynamic range (0.07–29.09mmHg) than the commercial device (2–10mmHg). Although this new air-pulse sensory testing equipment appears to be promising, the device has been tested only by his group (Hammer & Barlow, 2010; Hammer, Murphy, & Abrams, 2013) and is not commercially available.

Based on the literature review and the findings of the preliminary investigation, this dissertation project was directed at investigating the potential of the touch method to be a clinically relevant laryngeal sensory test. The touch method, however, has been criticized as an inaccurate approach (Clayton et al., 2014). Firstly, the intensity of the test stimulus exerted by different examiners may be inconsistent, making test results unreliable. Secondly, the expected responses elicited by the touch method are uncertain.

1.4 Study aims

The primary purpose of Study 1 in this dissertation was to investigate the variability in the pressure delivered by clinicians using the touch method and their reliability in judging the absence/presence of the laryngeal adductor reflex in response to a touch. The secondary purpose of Study 1 was to report the types of various subject responses to the touches.

The primary aim of Study 2 in this dissertation was to determine whether or not an absent LAR in response to pressure applied to the laryngeal mucosa with the tip of an endoscope was associated with penetration/aspiration in patients with dysphagia. The secondary aim of Study 2 was to determine whether or not an absent LAR was associated with pneumonia in patients with swallowing disorders.

2. STUDY ONE

A pilot study of the variability of measurements of the pressure exerted by the tip of laryngoscopes during laryngeal sensory testing

ABSTRACT

Purpose: Clinicians often test laryngeal sensory function by touching the laryngeal mucosa with the tip of the flexible laryngoscope. However, the pressure applied to the larynx using this touch method is unknown, and the expected responses elicited by this method are uncertain. The purpose of this study was to investigate the variability in the pressure delivered by clinicians using the touch method. We also reported on the types of various subject responses to the touches.

Methods: A fiberoptic pressure sensor (OPP-M; OpSens) was passed through the working channel of a laryngoscope, with its tip positioned at the distal port of the channel. Eight healthy adults were tested, each by two examiners. Each examiner touched the mucosa near the left arytenoid three times. The fiberoptic sensor recorded the pressure exerted by each touch. An investigator noted various subject responses to the touches. From the recorded videos, two raters independently judged the absence/presence of the laryngeal adductor reflex in response to touch.

Results: Forty-six pressure measurements were successfully obtained, which ranged from 17.9mmHg to 350.0mmHg. The mean of the pressure measurements exerted by Examiner 1 was lower than that exerted by Examiner 2. The most frequently observed response to touch was positive examinee report (93.5% of trials) followed by the presence of a laryngeal adductor reflex (87.0% of trials).

Conclusion: Pressure exerted when touching the arytenoids with a laryngoscope was highly variable, indicating potential diagnostic inaccuracy in determining sensory function in patients with mild sensory impairment.

2.1 Background

Sensory input from the laryngeal mucosa is essential for triggering protective airway reflexes (Bradley, 2000). These reflexes elicited include a cough (Canning et al., 2014; J. G. Widdicombe, 1995), gag, swallow, and the laryngeal adductor reflex (LAR). The LAR is a brainstem reflex that manifests as a brief vocal fold closure in response to sensory input to the laryngeal mucosa. Reduced laryngeal sensory detection, sensory processing, and/or motor output may fail to trigger those protective reflexes (Aviv et al., 1998; Aviv et al., 2002; Phua, McGarvey, Ngu, & Ing, 2005; Shock et al., 2015; Sulica, Hembree, & Blitzer, 2002), thereby increasing risk for aspiration and subsequent airway complications in patients with dysphagia (Aviv, Sacco, Mohr et al., 1997; Kaneoka, Krisciunas, Walsh, Raade, & Langmore, 2014; Onofri et al., 2014). Thus, in order to identify patients who are at high risk for aspiration, laryngeal sensory testing has been recommended as a part of the endoscopic swallowing examination (Langmore et al., 1988).

Laryngeal sensation is often tested by lightly and briefly touching the laryngeal mucosa with the tip of a flexible laryngoscope (the touch method). Several studies have described the locations to touch for testing sensation: the aryepiglottic folds (Langmore et al., 1988; Leow et al., 2012; Onofri et al., 2014), arytenoids (Langmore et al., 1988; Onofri et al., 2014), or epiglottis (Langmore et al., 1988). Studies have reported five

acceptable positive responses to the touch of an endoscope: patient report when they feel the touch (Kaneoka et al., 2015; Leow et al., 2012; Sato et al., 2002), an LAR (Domer et al., 2013; Onofri et al., 2014), a cough, a gag, or a swallow (Langmore et al., 1988; Leow et al., 2012). However, several issues remain unclear regarding the touch method. First, the intensity of any touch is unknown, and may be inconsistent across trials. Touches of variable pressure may not allow examinees to respond consistently across trials, making the diagnosis of sensory deficit unreliable. Second, it is unknown which form of response (i.e. examinee report, the LAR, cough, gag, or swallow) is the most commonly observed when applying a touch. Third, inter-rater reliability in judging the absence/presence of the LAR has not been tested.

The primary purpose of this study was to investigate the variability in the pressure delivered by clinicians using the touch method. We hypothesized that there would be a large range of pressure applied to the laryngeal mucosa using the endoscopic touch method. We also hypothesized that the pressure exerted by different examiners would be different. The secondary purpose of this study was to report the types of various subject responses to the touches. The third purpose of the study was to test clinicians' reliability in judging the absence/presence of the LAR in response to a touch. We hypothesized that clinicians' reliability would be acceptable in judging the absence/presence of the LAR.

2.2 Methods

This study was conducted in the Otolaryngology outpatient clinic of an urban teaching hospital. The study protocol was approved by the Institutional Review Board

(Ref. number: H33037) and written informed consent was obtained from all participants.

2.2.1 Participants

A total of 8 healthy adults with no history of trauma or surgery to the neck or larynx, no history of laryngeal malformation, no history of neurologic disease and no history of dysphagia were recruited. All participants demonstrated the ability to understand verbal and written instructions in English. Individuals with an allergy to lidocaine and pregnant women were excluded from the study.

2.2.2 Equipment interface

Figure 1 presents the equipment interface. A flexible channel fiberoptic nasolaryngoscope (FNL-10RAP; PENTAX, Lincoln Park, New Jersey, USA) was utilized for sensory testing. A fiberoptic micropressure sensor (OPP-M; OpSens, Quebec, Canada), which has been designed for human and animal physiological pressures ranging from -50.0mmHg to 350.0mmHg, was inserted through the working channel of the endoscope (FNL10-RAP; PENTAX). The tip of the sensor was positioned at the distal port of the open channel. The proximal end of the micropressure sensor cable was connected to a signal-reading device (LIFESens; OpSens). LIFESens is a signal conditioner that is also optimized for measuring physiological pressures in humans and animals, and is compatible with the fiberoptic micropressure sensor. The device was then connected to the Digital Swallowing Work Station (DSW; Model 7200, PENTAX). The

channel scope was coupled with a light source (LH-150; PENTAX) and was connected to the Pentax camera system (PSV-4000; PENTAX). The camera system was then connected to the Digital Swallowing Work Station where pressure readings and video images of the larynx were captured simultaneously. The videos were recorded at a rate of 30 frames per second. Calibration of the sensor was implemented using the calibration function of LIFESens before each exam according to the manufacturer instructions.

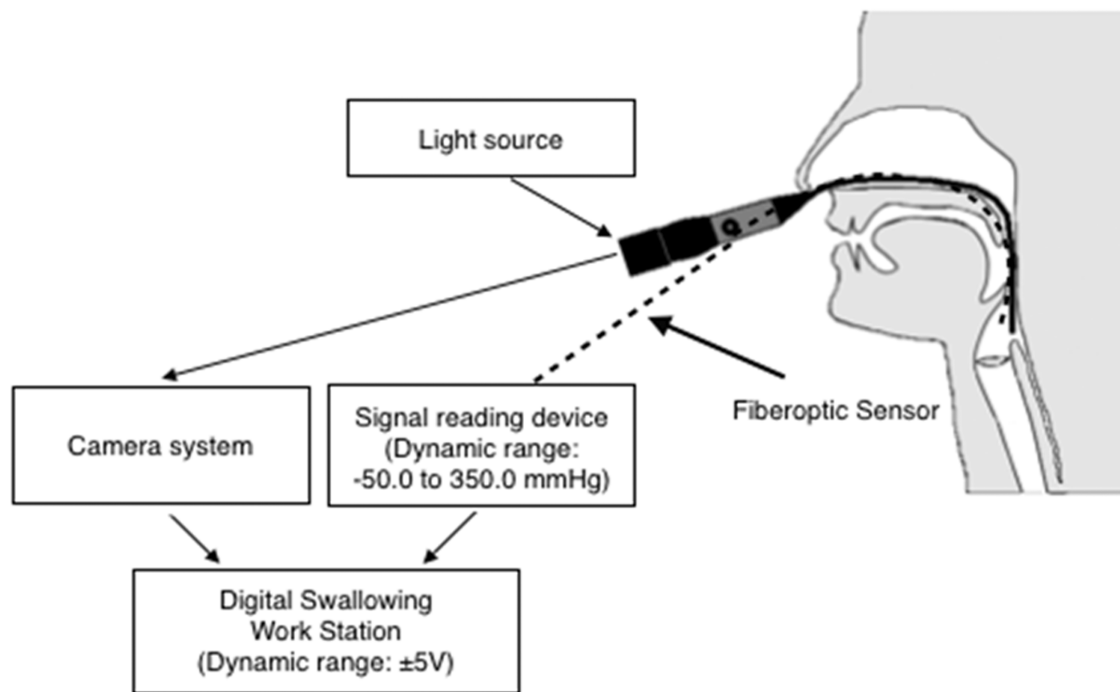


Figure 1 Equipment interface

2.2.3 Preliminary testing

The study protocol was tested by two speech language pathologist authors who served as examiners on one examinee. In addition to the study set-up as described above, a second videolaryngoscope (VNL-1070STK; PENTAX) was connected to the Digital Swallowing Work Station, and was used as a “monitoring scope.” The monitoring scope was only used in the preliminary testing phase to determine when the primary scope touched the laryngeal mucosa. The monitoring scope was passed by the first examiner through the examinee’s nostril and positioned so that the larynx could be fully visualized throughout the procedure. The channel scope with the sensor was then passed by a second examiner through the other nostril and positioned so that the larynx could be fully visualized. At this time, the pressure reading from the sensor was shown on the monitor of the Digital Swallowing Work Station and the screen of the Lifesens program and verified to be at zero. Then the examiner lightly and briefly touched the mucosa near the left arytenoid (Langmore et al., 1988). Figure 2 shows that the monitoring scope captured the moment when the sensory scope touched the laryngeal mucosa (A). The area highlighted in blue in Figure 2 (A) indicates the location the examiners targeted for applying a touch. When the scope touched the mucosa surrounding the arytenoid, the view from the channel scope was blocked by the mucosal surface (B). We therefore defined the pressure levels exerted by a touch as the maximum pressure that occurred during the time that the laryngoscopic view was completely blocked by the laryngeal mucosa (C).

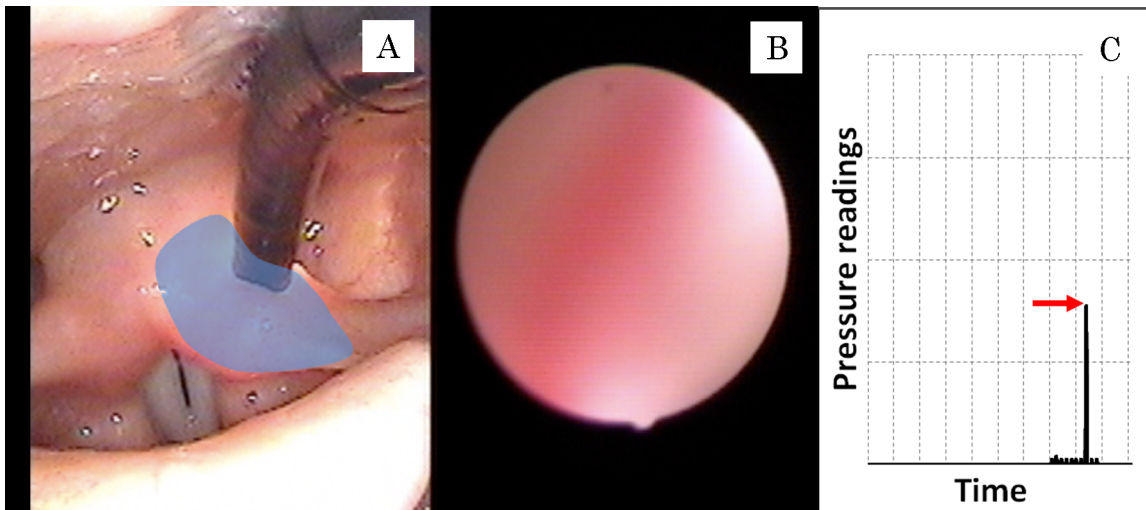


Figure 2 Laryngoscopic view of a touch and the corresponding pressure reading recorded on the Digital Swallowing Work Station

A: Laryngoscopic view from the monitoring scope capturing the moment when the sensory scope came into contact with the laryngeal mucosa.

B: Laryngoscopic view from the sensory scope used for testing. The entire view is obstructed by the laryngeal mucosa.

C: A schematic image of pressure readings on the Digital Swallowing Work Station. The arrow indicates the maximum voltage level reached while the scope is in contact with the mucosa.

2.2.4 Data collection

Data were collected from eight healthy adult participants (4 males, 4 females; mean age \pm 1SD = 39.4 \pm 10.6 years). The two examiners tested laryngeal sensory processing on each participant. Examiner 1 had two years of prior experience and Examiner 2 had more than 20 years of experience using the touch method. Topical

anesthesia (0.2mL of 4% lidocaine hydrochloride) was sprayed in the left nostril of each participant. The channel scope, which stored the pressure sensor in its working channel, was lubricated with K-Y Jelly[®] and then passed by the first examiner through a participant's left nostril into the pharynx. Participants were prompted to vocalize a sustained "ee" for 2–3 seconds to assess vocal fold mobility. Then, the participants were instructed to close their eyes to be blinded to the monitor showing the endoscopic view and to press a hand-held buzzer as soon as they felt each touch. One trial touch was applied to the left arytenoid in order to give the participants an opportunity to practice detecting what a "touch" felt like. Then the formal testing began.

The first examiner lightly and briefly touched the mucosa of the left arytenoid with the tip of the laryngoscope three times in total. The subject rested with the scope in place for at least 30 seconds between touches. After each attempt, the examiner indicated whether or not they thought they had made adequate contact on the arytenoid with a verbal code unknown to the participant. If the examiner indicated that they thought the sensory scope did not make contact on the arytenoid, the pressure reading and participant report of the attempt were discarded, and the examiner repeated the trial. Then the second examiner performed the sensory testing in the same manner. The order of the examiners was counterbalanced across the participants. The scope remained in the participant's nostril throughout the procedure. A third speech language pathologist, the author who served as an observer, recorded the participant's report, as well as presence or absence of a responsive cough, gag, and/or swallow. The two examiners were blinded to their applied pressure readings until they completed testing on all eight participants. However,

if the pressure measurement of any touch reached or exceeded the maximum measurable level (350.0mmHg), the observer notified the examiner that the touch had exceeded the ceiling. This was to attempt to limit the number of additional unquantifiable measurements. Every examination was monitored for adverse events, including any instances of vasovagal episodes, laryngospasms, or laceration of the mucosa.

Absence/presence of the LAR response was judged for each recorded touch by two additional speech language pathologists, with at least 10 years of experience with the touch method, who had not been present for the testing. When a brief adductor of the arytenoids or vocal folds was observed, the LAR was determined to be present. The judgments were made by reviewing the recorded videos frame-by-frame. In the case of disagreement, a third independent clinician's judgment was used.

2.2.5 Data analysis

The range of pressures exerted by the two examiners was described in order to demonstrate the variability of the intensity of the touches. The variability of pressure measurements exerted by the two examiners were compared using an analysis of variance, after adjusting for subject variability. The repeated measures of pressure for each subject exerted by the two examiners were assumed to be equally correlated, implying an exchangeable correlation structure. Thus, the generalized estimating equation approach was used for the analyses. Frequency of absence/presence of participant report, the LAR, cough, gag, or swallowing reflexes in response to touch was reported. Reliability between the two raters in judging absence/presence of the LAR was tested using the Kappa

statistic. Statistical analyses were performed on SAS[®] (version 9.4; SAS Institute Inc. Cary, NC, USA).

2.3 Results

All eight participants completed the study protocol. Complete bilateral vocal fold adduction was judged to be normal in all participants as judged from their vocalized sustained “ee.” In total, the examiners judged that 48 touches (24 touches per examiner) were successfully applied out of 56 attempts (Table 1). No vasovagal episodes, laryngospasms, or lacerations of the mucosa occurred during the testing.

2.3.1 Pressure measurements

Of those 48 touches, two pressure measurements were not recorded due to errors with the data acquisition system. Forty-six pressure measurements ranged from 17.9mmHg to 350.0+mmHg; three pressure values of the 46 readings exceeded the maximum measurable level of the sensor (350.0mmHg). As a result, 43 pressure measurements were used for the following statistical analyses. The mean and standard deviation of 43 pressure measurements obtained was 110.9 ± 90.7 mmHg. The mean pressure exerted by Examiner 1 and Examiner 2 was 89.4 ± 75.8 mmHg and 133.5 ± 100.9 mmHg respectively. The analysis of variance using the generalized estimating equation approach revealed that the mean pressure exerted by Examiner 1 was significantly lower than the mean pressure exerted by Examiner 2, after adjusting the subject variability ($p=0.03$). The variability in repeated pressure measurements within each subject was not significant, after adjusting the examiner variability ($p= 0.20$).

Subject	Sex	Age	Trial	Examiner	Pressure (mmHg)	Examinee				
						report	LAR	Swallow	Cough	Gag
1	female	39	1	1	77.0	present	positive	present	absent	absent
1			2	1	24.9	present	positive	absent	absent	absent
1			3	1	63.0	present	positive	absent	absent	absent
1			4	2	21.4	present	positive	present	absent	absent
1			5	2	350.0+	present	positive	present	absent	absent
1			6	2	.	present	positive	present	absent	absent
2	female	42	1	1	85.4	present	positive	absent	absent	absent
2			2	1	.	present	positive	present	absent	absent
2			3	1	42.0	present	positive	present	absent	absent
2			4	2	108.5	present	positive	absent	absent	absent
2			5	2	32.9	present	cannot judge	absent	absent	absent
2			6	2	136.2	present	positive	absent	absent	absent
3	male	41	1	2	232.4	present	positive	absent	absent	absent
3			2	2	246.8	present	positive	absent	absent	absent
3			3	1	273.7	absent	positive	absent	absent	absent
3			4	1	309.8	present	positive	absent	absent	absent
3			5	1	49.0	present	positive	absent	absent	absent
3			6	2	298.2	present	positive	absent	absent	absent
4	male	35	1	1	143.5	present	positive	absent	absent	absent
4			2	1	93.8	present	positive	absent	absent	absent
4			3	1	127.4	present	positive	absent	absent	absent
4			4	2	132.0	present	positive	absent	absent	absent
4			5	2	350.0+	present	positive	absent	absent	absent
4			6	2	283.5	present	positive	absent	absent	absent
5	female	25	1	1	60.6	present	positive	absent	absent	present

5			2	1	79.1	present	positive	present	present	present
5			3	1	17.9	present	positive	present	present	absent
5			4	2	311.5	present	positive	present	present	absent
5			5	2	263.6	present	positive	present	present	present
5			6	2	157.2	present	positive	absent	present	absent
6	male	62	1	1	132.7	present	cannot judge	absent	absent	absent
6			2	1	56.4	present	positive	present	absent	absent
6			3	1	131.3	present	cannot judge	absent	absent	absent
6			4	2	97.3	present	cannot judge	absent	absent	absent
6			5	2	25.2	present	positive	absent	absent	absent
6			6	2	105.4	present	positive	absent	absent	absent
7	female	37	1	2	134.1	present	positive	present	absent	absent
7			2	2	34.0	present	positive	present	absent	absent
7			3	2	37.8	present	positive	present	absent	absent
7			4	1	71.1	present	positive	present	absent	absent
7			5	1	43.8	present	positive	absent	absent	absent
7			6	1	17.9	present	positive	present	absent	absent
8	male	33	1	2	104.0	present	positive	absent	absent	absent
8			2	2	21.0	present	positive	absent	absent	absent
8			3	2	21.4	present	cannot judge	absent	absent	absent
8			4	1	44.1	absent	cannot judge	absent	absent	absent
8			5	1	350.0+	present	positive	absent	absent	absent
8			6	1	22.4	absent	positive	absent	absent	absent

Table 1 Pressure measurements and examinees' responses

2.3.2 Type of responses

Table 2 shows the absence or presence of each type of response to the 46 touches. Examinee's report was the most frequently observed positive response, followed by the LAR, the swallowing reflex, the cough reflex, and the gag reflex.

2.3.2.1 Examinee's report

Examinees reported that they felt the touch in 43 trials (93.5% of a total of 46 touches). The three touches that were not reported by the subjects had pressure readings of 22.4mmHg, 44.1mmHg and 273.7mmHg. Two of these three unreported touches did, however, elicit LARs. The endoscopic view of the third unreported touch was not of adequate quality to determine whether a LAR had or had not been elicited (Table 1).

2.3.2.2 The Laryngeal Adductor Reflex

The LAR was consistently observed in response to the touch when the laryngoscopic view was clear. However, judgment of the absence/presence of the LAR was not possible in six trials (13.0% of the total trials) due to a limited view of the larynx after the touch was applied. This failure in capturing the LAR occurred in one female (Subject 2) and two male subjects (Subject 6 and Subject 8). The pressure values exerted by those six touches ranged from 21.4mmHg to 131.7mmHg, indicating that the capture failure of the LAR occurred regardless of the level of the pressure applied to the laryngeal mucosa.

2.3.2.3 Swallowing reflex

The swallowing reflex occurred in 16 trials (34.8% of the total trials). Among male subjects, there was only one instance in which a touch trial elicited a swallow. Conversely, four females swallowed in response to 15 touches in total. The pressure values of the touches that evoked the swallowing reflex ranged from 17.9mmHg to 350.0+mmHg. This wide range of pressures that evoked the swallowing reflex also indicated that the occurrence of the swallowing reflex may not depend on the level of the pressure applied to the larynx.

2.3.2.4 Cough reflex

The cough reflex occurred in five trials in one female subject only (Subject 5). The pressure measurements that evoked the cough reflex in the subject ranged from 17.9mmHg to 311.5mmHg. This wide range of pressures that evoked the cough reflex also indicated that the reflex could occur regardless of the intensity of the touch applied to the laryngeal mucosa.

2.3.2.5 Gag reflex

The gag reflex also occurred in three trials in one female subject (Subject 5) who presented the cough reflex in response to touch. The pressure measurements that evoked the gag reflex in the subject ranged from 60.6mmHg to 311.5mmHg. This wide range of pressure that evoked the gag reflex also indicated that the reflex could occur regardless of the strength of the pressure applied to the mucosa.

Type of response	Number of responses (%)		
	Present	Absent	Could not be determined
Examinee report	43 (93.5)	3 (6.5)	0
LAR	40 (87.0)	0 (0.0)	6 (13.0)
Swallow	16 (34.8)	30 (65.2)	0
Cough	5 (10.9)	41 (89.1)	0
Gag	3 (6.5)	43 (93.5)	0

Table 2 Types of response

2.3.3 Inter-rater reliability for judging the LAR

Inter-rater reliability for judging the absence/presence of the LAR was tested on the 40 trials that provided adequate views. The analysis yielded a kappa coefficient of 0.52 (95% CI=0.29–0.98), indicating a moderate agreement between the clinicians.

2.4 Discussion

The study investigated the variability in the pressure delivered by clinicians using the touch method. The study also reported the types of various subject responses to the touches. Additionally, clinicians' reliability in judging the absence/presence of the LAR in response to a touch was tested. The results showed that intensity of touches was inconsistent across all trials. The pressure levels exerted by the touches ranged from 17.9mmHg to over 350.0mmHg. This range is important to highlight because a range of this magnitude may result in diagnostic inaccuracy. Aviv's work previously reported that if a patient does not elicit a LAR with an air pulse pressure of 6mmHg, then the patient has a severe sensory impairment (Aviv, Sacco, Thomson et al., 1997; Aviv et al., 1997). The current study found the mean pressure level exerted by directly touching the arytenoid was 110.9 ± 90.7 mmHg — much higher than 10mmHg, which is the maximum level delivered by the air pulse method. In the touch method, the direct contact pressure between the probe of the pressure sensor and the laryngeal mucosa is recorded whereas in the air pulse method, the reported values are the pressures of the air pulse produced by the air pulse stimulator. Clearly, the values obtained by these two different techniques are not comparable due to the fundamental differences in pressure acquisition. If we could generalize Aviv's definition of severe sensory deficits, then a person who exhibited the LAR in the current study may still have a 'sensory deficit'. However, it also suggests that if a person does not display the LAR, then it is highly probable that they do indeed have a peripheral or central sensory processing deficit. Thus, it is possible that the direct contact method is useful clinically when investigators aim to identify patients who have very

severe laryngeal sensory deficits.

The study also revealed that there was a difference between the means of the pressure levels of touch exerted by the two examiners. The variability in repeated pressure measurements within each subject was not significant, after adjusting the examiner variability. This means that the variability in pressure measurements was related to difference in examiners' technique and not from different characteristics of the subjects tested. One possible explanation for this difference is examiners' years of experience with the touch method; Examiner 1 had two years of experience vs. Examiner 2 had more than 20 years of experience.

With regard to types and consistency of patient response, the LAR consistently occurred in response to the touch in healthy adults in this sample. On the other hand, cough, gag, and swallowing reflexes did not occur consistently. Moreover, the occurrence of the reflexive responses did not seem to be related to the intensity of the touch. For example, one subject presented a cough in response to a touch, but the subject did not cough in response to another touch that exerted much higher pressure than the one that previously evoked a cough. This finding suggests that the absence of the LAR can be a reliable marker of sensory dysfunction, while cough, gag, and swallowing reflexes should not be used as a marker of sensory dysfunction. One drawback of using the LAR as a marker for the sensory function in the touch method, however, is that the absence/presence of an LAR was not able to be rated in 13.0% of the total attempts due to poor visualization. This generally occurred because a clear endoscopic view of a quick, brief movement of the vocal folds was sometimes difficult to obtain when the

laryngoscope was positioned over the arytenoid or touching the surface. Recall that in this study, the LAR was judged after the examination by two independent raters viewing the recorded exam, playing the video frame by frame. Thus, when viewing and rating the results in a live examination, examiners may not be able to evaluate sensory processing function consistently.

There were several limitations to this investigation. First, our study included only two examiners. There is likely to be more variability in pressures when multiple examiners with varying years of experience performing the touch method. Second, three pressure values exceeded the maximum measurable values of the fiberoptic sensor. Therefore, the true maximum values that were exerted by the two examiners could have been much higher than 350.0mmHg. Finally, it may be argued that the dose of lidocaine might have altered the results by depressing sensation although there is good evidence suggesting that the limited use of topical anesthetic agents does not affect swallowing function in patients with dysphagia (O'Dea et al., 2015) or sensory function in healthy adults (Kamarunas, McCullough, Guidry, Mennemeier, & Schluterman, 2014). In addition, it most likely did not affect the occurrence of the LAR in responses to a touch of the scope because the touch was a supra-threshold stimulus and their responses were always positive (i.e., a presence of the LAR).

2.5 Conclusion

The study investigated the variability in the pressure delivered by clinicians using the touch method. It demonstrated a wide range of pressures and inconsistent pressure

levels between examiners. This may suggest that the touch method has low specificity, and that it may result in imprecise diagnostic information when testing individuals with mild-moderate sensory processing deficits. This technique, however, may be quite sensitive in detecting gross sensory processing deficits if a person does not evoke the LAR to the touch stimulus. Given the frequent use of the touch method in clinical endoscopic swallowing evaluation, further research is needed to establish the validity and utility of this diagnostic tool.

3. STUDY TWO

The association between laryngeal sensory deficits, aspiration, and pneumonia in patients with dysphagia

ABSTRACT

BACKGROUND: The purpose of this study was to examine if laryngeal sensory deficits are associated with penetration/aspiration or pneumonia in patients with dysphagia.

METHODS: Inpatients at a teaching hospital with clinical symptoms of dysphagia were recruited for this study upon referral to the Otolaryngology clinic for a swallowing evaluation. Otolaryngologists observed the status of secretions and tested laryngeal sensation by touching each arytenoid with the tip of the laryngoscope (the touch method). The patients were then asked to swallow 3–5mL grape gelatin and 3–5mL colored water. All procedures were video-recorded. Absence/present of the laryngeal adductor reflex as a marker of laryngeal sensory function, and penetration/aspiration of pharyngeal secretions, gelatin, and water were noted by independent raters on the recorded videos. A diagnosis of pneumonia during the patient's entire hospital stay was determined by a review of the hospital's medical records. Statistical analyses were performed using Fisher's exact test.

RESULTS: Sixty-one patients were included in this study. Twenty-one patients (34.5%) showed reduced laryngeal sensation. No association was found between reduced laryngeal sensation and penetration or aspiration. There was, however, a significant association between reduced laryngeal sensation and pneumonia development ($p < 0.01$). Patients with reduced laryngeal sensation had 6.8 times the risk of developing pneumonia

as compared to patients with normal laryngeal sensation (OR = 6.75; 95% CI = 1.76–25.96).

CONCLUSIONS: Laryngeal sensory deficits, as determined by the touch method, were associated with occurrence of pneumonia. Sensory testing using the touch method appears to be valuable for predicting pneumonia risk in patients with dysphagia.

3.1 BACKGROUND

Loss of sensory input from the laryngeal area may fail to trigger airway protective reflexes, resulting in aspiration of food, liquids (Onofri et al., 2014; Sato et al., 2002) or oropharyngeal secretions (Donzelli, Brady, Wesling, & Craney, 2003; Murray, Langmore, Ginsberg, & Dostie, 1996; Warnecke et al., 2009). Patients with dysphagia often demonstrate reduced laryngeal sensation. Thus, testing laryngeal sensation has been recommended as part of fiberoptic endoscopic evaluation of swallowing (FEES) in order to identify patients at high risk for aspiration (Langmore et al., 1988).

Clinicians test laryngeal sensation by applying light and brief touches to the laryngeal mucosa with the distal end of a flexible laryngoscope (the touch method). This direct mechanical stimulation to the laryngeal mucosa may elicit a cough, gag, swallow, or the laryngeal adductor reflex (LAR; (Domer et al., 2013; Leow et al., 2012). If any of these reflexes are triggered in response to touch, laryngeal sensation is judged to be grossly intact (Langmore et al., 1988).

The clinical reliability of this simple technique, however, has been questioned (Clayton et al., 2014). Our preliminary investigation, as described in Study 1 of this

dissertation, demonstrated that the pressure levels of the touches applied to the laryngeal mucosa varied a great deal, although all of them were above the threshold value identified by Aviv and others (Aviv et al., 1993). This finding suggests that patients may not elicit different reflexes consistently across trials. The study, however, found that only the LAR did consistently occur when the touches were applied to healthy adults, while cough, gag, and swallowing reflexes occurred in response to only some of the touches applied, suggesting that absence of cough, gag, or swallowing reflexes should not be interpreted as a sign of reduced laryngeal sensation. On the other hand, if a person does not demonstrate a LAR to the touch stimulus, sensory processing deficits are indicated.

Using this touch method, a previous study found a correlation between sensory deficits as determined by the absence/presence of the LAR and increased likelihood of penetration/aspiration in post stroke patients (Onofri et al., 2014). The question remains whether or not the sensory deficits identified by the touch method are predictive of aspiration in individuals with dysphagia in populations other than stroke. It is also unknown if failure to trigger the LAR in response to touch is associated with increased risk of pneumonia. If the association between absent LAR and aspiration can be generalized to other patient populations, then any patient with laryngeal sensory deficits, regardless of whether aspiration was visualized with limited bolus trials during FEES, may warrant more conservative steps regarding diet and other rehabilitation recommendations. If an absent LAR is predictive for pneumonia, more aggressive preventative interventions for pneumonia should be provided for patients who do not demonstrate the LAR during the touch method.

The aim of this study was to determine whether or not an absent LAR in response to pressure applied to the laryngeal mucosa with the tip of an endoscope is associated with penetration/aspiration of food, liquid, or pharyngeal secretions in patients with dysphagia. The study also aimed to determine whether or not an absent LAR is associated with pneumonia in patients with swallowing disorders. We hypothesized that sensory deficits identified by the touch method would be associated with aspiration and pneumonia in patients with dysphagia with various medical diagnoses.

3.2 METHODS

This study was conducted in the Otolaryngology Outpatient Clinic of an urban teaching hospital in Tokyo, Japan. The study protocol was approved by the Institution Review Board (Ref No. 10781). Written informed consent was obtained from all participants or approved family members.

3.2.1 Participants

Inpatients with clinical symptoms of dysphagia were consecutively screened as they were referred to the Department of Otolaryngology for a swallowing evaluation from April 2015 through February 2016. The swallowing assessment was performed by one of three otolaryngologists as part of the standard care practices of the hospital. Examiners 1, 2, and 3 had 10, 13, and 9 years of prior experience using the touch method respectively. Patients were excluded from the study if they had: 1) unstable state of consciousness as measured by Glasgow Coma Scale (GCS; GCS score < 13 point

(Teasdale & Jennett, 1974; Teasdale et al., 2014), 2) inability to sit upright and be transferred to the exam room of the otolaryngology clinic, 3) history of surgical removal of the arytenoids, 4) incomplete vocal fold closure identified during laryngoscopic evaluation (Leder, Suiter, Duffey, & Judson, 2012), 5) inability to understand the verbal instructions involved in endoscopic evaluation of swallowing with sensory testing, or 6) if they or their family did not provide the consent for participating the study.

3.2.2 Equipment

Two different models of laryngoscopes (Olympus ENF VH, ENF-VQ: both with diameter = 3.9 mm; Olympus Medical Systems Corporation; Tokyo, Japan) were utilized for sensory and swallowing testing. FEES images were obtained using light sources (CLV-S40Pro, Olympus Medical System Corporation) and video recording and archiving systems (Olympus OTV-S7Pro, Olympus Medical System Corporation).

3.2.3 Procedure

Patients were seated upright in a chair or wheel chair. Topical nasal vasoconstrictor (0.1mL of 0.02% epinephrine) and anesthesia (0.2mL of 4% lidocaine) were sprayed in the nostril that would be used. The scope was passed trans-nasally to the pharynx. Participants were prompted to vocalize a sustained “ee” for 2–3 seconds to assess vocal fold mobility. Then, the participants were instructed to close their eyes to be blinded to the monitor showing the endoscopic view. The otolaryngologist then lightly

and briefly touched the mucosa over the left and right arytenoids with the tip of the laryngoscope. The patients rested for at least 5 seconds between touches. Next, a FEES was performed. The patients were then asked to swallow two trials each of 1) 3mL grape gelatin (Otsuka Pharmaceutical Co., Ltd. Tokyo, Japan), 2) 5mL grape gelatin, 3) 3mL thin water, and 4) 5mL thin water. All boluses were delivered using a syringe. The water was colored purple with Pyoktanin for ease of visualization. When examiners observed that a patient aspirated or if the examiners were concerned that a patient would aspirate in upcoming trials, the second trial of that consistency (the larger volume) was not administered.

The videos were recorded at a rate of 30 frames per second. Two raters (a speech language pathologist and a physiatrist) who were not involved in the endoscopic evaluation independently analyzed the video images of swallows by playing them frame-by-frame. Absence/presence of the LAR was noted for the left and right arytenoids, or unknown if it could not be visualized on the video. When the LAR did not occur at one or both of the two test locations, laryngeal sensation was determined to be reduced. Pooling of oropharyngeal secretions in the pharynx and larynx was examined when phonatory and airway protection ability were observed prior to the presentation of test food materials (Donzelli et al., 2003; Murray et al., 1996) for approximately 30 seconds. Penetration was defined as the invasion of test materials or pharyngeal secretions into the laryngeal vestibule above or to the level of the true vocal folds (Rosenbek, Robbins, Roecker, Coyle, & Wood, 1996a). Aspiration was defined as the invasion of test materials or pharyngeal secretions below the true vocal folds (Rosenbek et al., 1996a). Disagreement

between the two raters was resolved by discussion to determine the final judgment of the patients' sensory and swallowing statuses. Demographic characteristics were taken from the hospital's electronic medical records.

3.2.4 Outcomes

The primary outcome of this study was penetration and aspiration, as seen on the FEES. Presence/absence of penetration/aspiration of 3 or 5mL of gelatin, 3 or 5mL of water, and pharyngeal secretions were noted. The secondary outcome for the study was pneumonia. Pneumonia was defined by documented evidence of pneumonia confirmed on chest radiography. The record of pneumonia diagnosis during the patient's hospital stay was extracted from the hospital's electronic medical records.

3.2.5 Data analyses

Data normality was assessed using Shapiro-Wilk test. Continuous demographic variables were compared with Wilcoxon rank sum test and categorical demographic variables were compared Pearson's chi-square test or Fisher's exact test between patients with normal or reduced sensation as represented by the presence or absence of the LAR. The association between normal or reduced sensation and presence or absence of penetration and aspiration for gelatin, water, and pharyngeal secretions was examined with Fisher's exact test. The association between laryngeal sensory status, penetration, and aspiration and the occurrence of pneumonia was also examined with Fisher's exact

test. Statistical analyses were performed on SAS[®] for Windows (version 9.4; SAS Institute Inc. Cary, NC, USA). Alpha = 0.05 was employed for the analyses.

3.3 RESULTS

3.3.1 Patient demographics

Ninety-four inpatients met the inclusion criteria for this study. Of those, 61 patients (64.9%) completed both 1) sensory testing on both left and right arytenoids and 2) swallowing evaluation of 3 and/or 5mL gelatin and 3 and/or 5mL water, with high quality images obtained for judging the absence/presence of the LAR as well as swallowing status. The other thirty-three patients were not included for analysis: eleven of these patients did not complete the sensory testing due to examiner decision; eleven patients did not provide a clear view of the larynx for determining presence/absence of the LAR; five patients were not tested adequately (the raters judged that the tip of the scope did not contact the mucosa over the arytenoids), and six patients were not given gelatin or water for the swallowing evaluation for safety concern due to the presence of very severe dysphagia with reduced ability to clear the airway.

Table 3 shows participant characteristics by laryngeal sensory status. The univariate analyses showed that there was no statistically significant difference in any of the characteristics between the participants who had normal and reduced laryngeal sensation, suggesting that none of the demographic variables could have been a potential confounder of the association between laryngeal sensory function, penetration/aspiration, or pneumonia (Table 3).

	Laryngeal sensory function (n=61), n (%)		p-value
	Normal n=40 (65.6)	Reduced n=21 (34.4)	
Age, median, years	70.0	74.0	0.31
Length of hospital stay, median, days	43.5	40.0	0.62
Gender			0.79
Male	22 (62.9)	13 (37.1)	
Female	18 (69.2)	8 (30.8)	
Diagnosis			0.30*
Neurologic	22 (71.0)	9 (29.0)	
Respiratory	2 (40.0)	3 (60.0)	
Cardiac	4 (80.0)	1 (20.0)	
Dermatologic	2 (50.0)	2 (50.0)	
Gastroesophageal	1 (25.0)	3 (75.0)	
Other	9 (75.0)	3 (25.0)	
Diet level at evaluation			0.35
Nil per os	7 (53.8)	6 (42.6)	
Modified diet	16 (61.5)	10 (38.5)	
Normal diet	17 (77.3)	5 (22.7)	
Liquid intake			0.36
Not allowed to take liquids	6 (50.0)	6 (50.0)	
Thickened liquids	15 (75.0)	5 (25.0)	
Thin liquids	19 (65.5)	10 (35.5)	

Nasogastric tube			0.74*
Absent	33 (67.3)	16 (32.7)	
Present	7 (58.3)	5 (41.7)	
Tracheostomy			0.53*
Absent	37 (66.1)	19 (33.9)	
Non-cuff-tracheostomy	3 (75.0)	1 (25.0)	
Cuff-tracheostomy	0 (0)	1 (100.0)	
Number of patients examined by examiner			0.70*
Examiner 1	29 (67.4)	14 (32.6)	
Examiner 2	8 (66.7)	4 (33.3)	
Examiner 3	3 (50.0)	3 (50.0)	

*Fisher's exact test

Table 3 Demographic characteristics

3.3.2 Laryngeal sensory testing

Forty of the 61 participants (65.6%) demonstrated normal laryngeal sensation and 21 participants (34.4%) showed reduced laryngeal sensory function. Of those 21 participants, 5 participants (23.8%) did not exhibit the LAR on either the left or right arytenoids, while 16 participants (76.2%) displayed the LAR on only one of the arytenoids.

3.3.3 Laryngeal sensation and penetration/aspiration

Of the 61 participants, gelatin penetration occurred in nine (14.8%) participants

and water penetration was observed in 17 (27.8%) participants. Penetration of secretions was found in nine (14.8%) participants. No significant association was found between reduced laryngeal sensation and penetration of gelatin (OR= 0.50; 95%CI= 0.09-2.64; p=0.48) or water (OR = 0.49; 95%CI=0.14-1.74; p=0.37) or pharyngeal secretions (OR= 1.65; 95%CI= 0.40-6.93, p=0.70; Table 4).

Of the 61 participants, gelatin aspiration occurred in one participant (1.6%); water aspiration was observed in eight participants (13.1%); aspiration of secretions was found in four (6.5%) participants. No significant difference was found between reduced laryngeal sensation and aspiration of gelatin (OR=0.98; 95%CI= 0.93-1.02;p=1.00) or water (OR=0.60; 95%CI= 0.11-3.25; p=0.70) or pharyngeal secretions (OR= 0.62; 95%CI= 0.06-6.32; p=1.00; Table 5).

Material	Penetration	Laryngeal sensation		Total	P value
		Normal (%)	Reduced (%)		
Gelatin	Absent	33 (54.1)	19 (31.1)	52 (85.2)	0.48
	Present	7 (11.5)	2 (3.3)	9 (14.8)	
Water	Absent	27 (44.3)	17 (27.9)	44 (72.2)	0.37
	Present	13 (21.2)	4 (6.6)	17 (27.8)	
Secretions	Absent	35 (57.4)	17 (27.8)	52 (85.2)	0.70
	Present	5 (8.2)	4 (6.6)	9 (14.8)	

Table 4 Laryngeal sensation and penetration

Material	Aspiration	Laryngeal sensation		Total	P value
		Normal (%)	Reduced (%)		
Gelatin	Absent	39 (64.0)	21 (34.4)	60 (98.4)	1.00
	Present	1 (1.6)	0 (0.0)	1 (1.6)	
Water	Absent	34 (55.7)	19 (31.2)	53 (86.9)	0.70
	Present	6 (9.8)	2 (3.3)	8 (13.1)	
Secretions	Absent	37 (60.7)	20 (32.8)	57 (93.5)	1.00
	Present	3 (4.9)	1 (1.6)	4 (6.5)	

Table 5 Laryngeal sensation and aspiration

3.3.4 Laryngeal sensation and pneumonia

Table 6 demonstrates the numbers of pneumonia cases by laryngeal sensory status.

Thirteen of 61 patients (21.3%) developed pneumonia during their hospital stay. There was a statistically significant difference in the number of pneumonia events between patients who had normal laryngeal sensation and patients who had reduced laryngeal sensation ($p= 0.01$). Patients with reduced laryngeal sensation had a 6.8 times increase in risk for developing pneumonia as compared with the patients who had normal laryngeal sensation (OR = 6.75; 95% CI =1.76–25.96).

Pneumonia	Laryngeal sensation		Total
	Normal (%)	Reduced (%)	
Absent	36 (90.0)	12 (57.1)	48 (78.7)
Present	4 (10.3)	9 (42.9)	13 (21.3)
Total	40	21	61

Fisher's exact test; $p < 0.01$

Table 6 Laryngeal sensation and pneumonia

3.4 DISCUSSION

The aim of this research study was to determine whether or not an absent LAR elicited by pressure applied to the laryngeal mucosa with the tip of an endoscope was associated with an increased likelihood of penetration/aspiration in patients with dysphagia. Contrary to a previous study finding in stroke patients with dysphagia (Onofri et al., 2014), no association was found between reduced laryngeal sensation and penetration/aspiration of food or liquid or pharyngeal secretions identified during FEES in this study sample. This study also aimed to determine whether or not an absent LAR was associated with pneumonia in patients with dysphagia. As hypothesized, an absence of the LAR was significantly associated with pneumonia in patients with swallowing disorders. This finding adds new evidence that the touch method has potential for identifying individuals with dysphagia at risk for pneumonia.

Unlike the previous report, the current study found no association between reduced laryngeal sensation identified with the touch method and penetration/aspiration

of food or liquid materials or pharyngeal secretions. These inconsistent results may be related to the different methodologies for sensory deficits with the touch method. First, in Onofri's study, laryngeal sensation was judged as normal when either the cough reflex or the LAR occurred in response to the touch stimulus. Our current study did not use the cough reflex as a marker of laryngeal sensory dysfunction since our prior study found that a cough response was inconsistent, even in healthy adults, in response to touch. Second, the examiners of this study may have been deliberately conservative by not providing any test materials when they deemed the patient (all of which were in acute medical status) to be at high risk for aspiration and pneumonia. Thus, the current study likely excluded the potential aspirators from the study sample. These methodological differences may have resulted in the inconsistency regarding the predictive value of the touch method for penetration/aspiration in patients with dysphagia.

In contrast to the lack of association between aspiration and the LAR, this study did find that an absence of the LAR (on either arytenoid) was associated with pneumonia in patients with dysphagia. The result supports the clinical utility in using laryngeal sensory testing as a means to identify those at higher risk for pneumonia. When evaluating patients with dysphagia and making decisions in their care, a highly predictive measure for pneumonia, which could be simply assessed during the swallowing evaluation, would be valuable.

A previous study done by Sato and colleagues also found the link between reduced laryngeal sensation as determined by the touch method and the occurrence of pneumonia in individuals with dysphagia in a rehabilitation hospital (Sato et al., 2002).

However, the results should be interpreted with caution due to the different stimulus delivery and outcome measures used in the previous study. In Sato's study, the authors asked the patients to verbally report when they felt the touch of the endoscope. A touch was then applied to the laryngeal surface of the epiglottis. Presence of patient's report, the swallowing reflex or “escaping reaction” (not defined in Sato’s study) was taken as a sign of intact laryngeal sensation. However, elderly patients, particularly in acute care hospitals, are often not able to reliably report feeling the touch due to reduced alertness or cognitive dysfunction. In addition, the epiglottis has not been verified as a reliable site to touch with the tip of a laryngoscope. Further, we found that even healthy adults did not always exhibit a swallow in response to a touch applied to the arytenoids (Study 1). Based on these previous findings, the current study recommends that in the touch method, a LAR should be used as a marker of sensory function when the arytenoids are touched.

We acknowledge some potential limitations of this study. First, it is possible that the study failed to detect a significant difference in aspiration risk in patients with and without sensory deficits in due to the low overall number of aspiration events. Previous studies have suggested that FEES protocols using small boluses (Butler et al., 2011) or limited numbers of swallow trial (Baijens, Speyer, Pilz, & Roodenburg, 2014) can underestimate the aspiration risk. Second, we used a referred population because patients in our hospital are not evaluated for swallowing disorders unless there are clinical symptoms. Thus, some potential selection biases may have been inherent in the study population. For example, patients with mild dysphagia who could have passed the

screening test for dysphagia may not have been referred to the otolaryngologists for instrumental evaluation. On the contrary, patients with severe medical conditions who were not able to sit upright were excluded from the study. The study also could not accommodate patients who presented with a poor laryngeal view during FEES or individuals who could not tolerate the touch method due to discomfort. Subjects who were judged to be at high risk for aspiration were not given larger boluses, which clearly limited the possible number of positive aspirators found in the evaluation. The potential selection bias might have affected the results of the current study.

3.5 CONCLUSION

The current study demonstrated no association between penetration/aspiration of gelatin or liquid or pharyngeal secretions identified during FEES and laryngeal sensory deficits determined by the touch method. Future research is warranted to determine if an absent LAR is associated with aspiration. The study also showed that the touch method has potential for predicting pneumonia in patients with swallowing problems. Based on these findings, clinicians should consider more conservative steps to managing the dysphagia when laryngeal sensation is reduced. Further, intensive measures for pneumonia prevention would be warranted.

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Scientific Memberships

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July 2016 General Secretary, Asia Pacific Society of Speech, Language, and Hearing

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Scholarship, Awards & Grants

February 2016 **Award: Poster Presentation Award**
Dysphagia Research Society 23rd Annual Meeting

June 2015 **Scholarship: ASHA Pathways Program**
The American Speech-Language-Hearing Association

March 2015 **Grant: Sumiko Okada International Fellowship Fund**
Japanese Society of Dysphagia Rehabilitation

September 2014 **Scholarship: ASHA Minority Student Leadership Program (MSLP)**
The American Speech-Language-Hearing Association

May 2013 **Grant: Dudley Allen Sargent Research Fund**
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Journal Publications

- Asako Kaneoka, Pisegna JM, Mirolo KV, Lo M, Saito H, Riquelme LF, LaValley MP, Langmore SE. *Prevention of Healthcare associated pneumonia with oral care in individuals without mechanical intubation*. 2015; *Infect Control Hosp Epidemiol*. 2015;10:1–8
- Asako Kaneoka, Gintas P Krisciunas, Kayo Walsh, Adele S Raade, Susan E Langmore: *A Comparison of 2 Methods of Endoscopic Laryngeal Sensory Testing: A Preliminary Study*. *The Annals of otology, rhinology, and laryngology*. 09/2014;
- Asako Kaneoka, Susan E Langmore, Gintas P Krisciunas, Katherine Field, Rebecca Scheel, Edel McNally, Michael J Walsh, Meredith B O'Dea, Howard Cabral: *The Boston Residue and Clearance Scale: Preliminary Reliability and Validity Testing*. *Folia phoniatica et logopaedica* : official organ of the International Association of Logopedics and Phoniatics (IALP). 07/2014; 65(6):312–317.
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Pisegna JM, Kaneoka A, Pearson WG, Kumar S, Langmore SE: Effects of non-invasive brain stimulation on post-stroke dysphagia: A systematic review and meta-analysis of randomized controlled trials. *Clin Neurophysiol* 127(1): 956–968, 2015.5

Invited Talks

- June 2016* Reconsideration of thickening liquids as an intervention for patients with dysphagia. The 17th Annual Meeting of Japanese Association of Speech-Language and Hearing Therapists. Kyoto, Japan
- May 2016* Filling the gap between research and clinical practice. Niigata Support Society of Dysphagia (NSSD) Annual Meeting. Niigata, Japan
- September 2015* Prevention of Healthcare associated pneumonia with oral care in individuals without mechanical intubation. The 21th Annual Meeting of the Japanese Society of Dysphagia Rehabilitation. Kyoto, Japan
- September 2013* The Boston Residue and Clearance Scale (BRACS): a preliminary study
The 19th Annual Meeting of the Japanese Society of Dysphagia Rehabilitation. Kurashiki, Japan
- February 2011* Anatomy and physiology of swallowing and examination of dysphagia
Kanto Dysphagia Clinical Seminar. Tokyo, Japan