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ORIGINAL ARTICLE

Vocal Fold Immobility and Aspiration Status: A Direct Replication Study

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Abstract The purpose of this direct replication study was to confirm the incidence of vocal fold immobility (VFI) and its relationship to pharyngeal dysphagia and aspiration. Using a single-group consecutively referred case series, a total of 2,650 participants underwent fiberoptic endoscopic evaluation of swallowing between August 2003 and December 2007. Main outcome measures included overall incidence of VFI and aspiration status, with specific emphasis on age, gender, etiology and pharyngeal phase bolus flow characteristics, and side of VFI (right, left, or bilateral). These data were compared to and then combined with the original study ($n = 1{,}452$) for a total of 4,102 participants. Results indicated that the incidence of VFI was 4.3% (112/2,650), i.e., 27% (31/112) unilateral right, 58% (65/112) unilateral left, and 14% (16/112) bilateral. Incidence of aspiration was 22% (580/2,650). Of those with VFI, 40% (45/112) aspirated, i.e., 42% (13/31) unilateral right, 37% (24/65) unilateral left, and 50% (8/16) bilateral. An individual with VFI had 2.50 times the odds of aspirating as someone without VFI (95% CI = 1.86–3.37). For liquid aspiration, the odds ratio (OR) = 2.41 (95% CI = 1.77–3.28), and for puree aspiration, OR = 2.08 (95% CI = 1.47–2.93). Left VFI occurred most frequently due to surgical trauma. Liquid was aspirated more often than a puree. Males exhibited VFI more often than females. Side of VFI and age were not factors that increased the incidence of aspiration significantly. It was confirmed that VFI is not an uncommon finding during dysphagia testing and, when present, increased the odds of aspiration compared to a population already being evaluated for dysphagia.

Keywords Deglutition · Deglutition disorders · Vocal fold immobility · Respiratory aspiration · Fiberoptic endoscopic evaluation of swallowing

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Previous research reported the incidence of vocal fold immobility (VFI), i.e., right, left, or bilateral, to be 5.6% (81 of 1,452 participants), and when VFI was present it was associated with a 15% increased incidence of aspiration, i.e., 29% (426 of 1,452) versus 44% (36 of 81) in a population already being evaluated for dysphagia [1]. Specifically, in this referred population of patients for dysphagia testing, a diagnosis of VFI conferred an odds ratio of 2.0 for aspiration (95% confidence interval [CI] = 1.3–3.2), i.e., twice the odds of aspiration, over the remaining population without VFI undergoing evaluation for dysphagia [2].

Although it is not an uncommon finding in patients referred for a dysphagia evaluation, VFI continues to generate interest regarding the association between it (unilateral or bilateral) and pharyngeal dysphagia and aspiration risk, especially in the acute-care setting [3–5]. Corroboration, therefore, with a larger sample size via direct replication is warranted.

Replication provides two basic functions essential for the substantive base of any scholarly field: verification or disconfirmation, i.e., a fact is not a fact until it is replicable [6]. Therefore, corroboration of the epidemiology of VFI, pharyngeal dysphagia, and aspiration status with a larger

sample size via direct replication would be beneficial. The purpose of the current direct replication study was to confirm the incidence of VFI and its relationship with pharyngeal dysphagia and aspiration status in a group already referred for dysphagia testing in the tertiary-care setting.

Methods

Subjects

This study was approved by the Human Investigation Committee, Yale University School of Medicine. A total of 2,650 consecutive inpatients, who were referred for dysphagia evaluation from a large urban tertiary-care teaching hospital in a prospective manner from August 2003 to December 2007, participated in this study. Fiberoptic endoscopic evaluation of swallowing (FEES) [7, 8] was used to determine both VFI and aspiration status. VFI, rather than vocal fold paralysis, was used to describe laryngeal function without stating or implying etiology [9]. No patient had prior laryngeal framework surgery, e.g., medialization thyroplasty. Participant demographics are given in Table 1.

Equipment

Equipment consisted of a 3.6-mm-diameter flexible fiberoptic rhinolaryngoscope (Olympus, ENF-P3), light source (Olympus, CLK-4), camera (ELMO, MN401E), color monitor (Magnavox, RJ4049WA01), and digital swallowing workstation (Kay Elemetrics Corp., Model 7200).

Procedures

All participants underwent FEES [7, 8] within 24 h of referral. The basic FEES protocol was followed with slight modifications. Briefly, each naris was examined visually and the scope passed through the most patent naris without administration of a topical anesthetic or vasoconstrictor to the nasal mucosa, thereby eliminating any potential adverse anesthetic reaction and assuring the endoscopist of a safe physiologic examination [10].

The distal tip of the endoscope was positioned just inferior to the velopharyngeal port allowing for visual observation of the base of the tongue, pharynx, and larynx. Repeated phonations of the vowel/ee/allowed for evaluation of vocal fold movement patterns. Swallowing was evaluated directly with food boluses of approximately 5 cc each. All patients were allowed to swallow spontaneously, i.e., without a verbal command to swallow [11].

Table 1 Participant demographics

Demographics	Leder and Ross (2005)	Present study	Combined data
Overall incidence of aspiration, *n* (%)	426/1,452 (29.3%)	580/2,650 (21.9%)	1,006/4,102 (24.5%)
Total sample of vocal fold immobility,[a] *n* (%)	81/1,452 (5.6%)	112/2,650 (4.3%)	193/4,102 (4.7%)
Vocal fold immobility participants			
Gender[a]	47M, 34F	63M, 49F	110M, 83F
Age[b] (years)	55.7, 59.7	61.4, 64.6	58.5, 62.1
Vocal fold immobility, *n* (%)	25 (31%) R, 49 (60%) L, 7 (9%) B	31 (27%) R, 65 (58%) L, 16 (14%) B	56 (29%) R, 114 (59%), 23 (12%) B
Aspiration, *n* (%)	11 (44%) R, 21 (43%) L, 4 (57%) B	13 (42%) R, 24 (37%) L, 8 (50%) B	24 (43%) R, 45 (40%) L, 12 (52%) B
Total incidence of aspiration,[a] *n* (%)	36/81 (44%)	45/112 (40%)	81/193 (42%)

R right, *L* left, *B* bilateral

[a] Spearman's rank order correlation: $P > 0.05$

[b] Pearson's product moment correlation: $P > 0.05$

The first food challenge consisted of three boluses of puree consistency (yellow pudding), followed by three liquid boluses (white skim milk), because these colors have excellent contrast with pharyngeal and laryngeal mucosa [12]. Bolus volumes ranged from 5 to 10 cc. A solid bolus (cracker) was given if the patient had adequate dentition for mastication.

Specific findings identified as contributing to pharyngeal dysphagia were (1) the stage transition characterized by depth of bolus flow to at least the vallecula prior to the pharyngeal swallow, (2) evidence of bolus retention in the vallecula or pyriform sinuses after the pharyngeal swallow, (3) laryngeal penetration defined as material in the laryngeal vestibule but not passing below the level of the true vocal folds either before or after the pharyngeal swallow, and (4) tracheal aspiration defined as the entry of material into the airway below the level of the true vocal folds [13]. No attempt was made to quantify the amount of aspiration. A safe swallow was defined as no aspiration during FEES.

A 100% nonblinded agreement between the endoscopist and an assisting health-care professional, e.g., physician, physician assistant, registered nurse, or respiratory therapist, was required to confirm both laryngeal physiology and aspiration status. The endoscopist who performed all FEES testing in the present study (SBL) participated in a recent investigation that reported an intrarater reliability of 100% for tracheal aspiration with FEES [12]. Subsequent confirmatory intra- and interrater reliability testing was performed prospectively with 73 additional cases. Two speech-language pathologists and an otolaryngologist experienced in interpreting FEES results independently and blindly reviewed the swallows on a digital swallowing workstation (Kay Elemetrics Corp., Model 7200). Using real-time analysis with repeat viewing as needed, both intra- and interrater reliability ratings for laryngeal physiology, bolus flow characteristics, and tracheal aspiration were 100%.

Statistical analysis was performed using SPSS v16.0 (SPSS Inc., Chicago, IL).

Results

Participant Demographics from the Original Leder and Ross Study [1], Current Direct Replication Study, and Combined Data

Table 1 lists participant demographics. For the current study, overall incidence of aspiration was 21.9% (580/2,650) and overall incidence of VFI was 4.3% (112/2,650), i.e., 63 males (mean age = 61.4 years) and 49 females (mean age = 64.6 years). In the subgroup of patients with VFI, 58% (65/112) exhibited unilateral left, 27% (31/112) unilateral right, and 14% (16/112) bilateral VFI. Of those with VFI, 40% (45/112) aspirated, i.e., 42% (13/31) unilateral right, 37% (24/65) unilateral left, and 50% (8/16) bilateral. An individual with VFI had 2.50 times the odds of aspirating as someone without VFI (95% CI = 1.86–3.37). Specifically, the odds ratio for liquid aspiration was 2.41 (95% CI = 1.77–3.28) and for puree aspiration it was 2.08 (95% CI = 1.47–2.93). The current data were in agreement with both the original research [1] and the combined results with respect to no significant differences found for the total sample of VFI and the total incidence of aspiration, as well as for gender- and age-based on VFI.

Categories of VFI from the Original Leder and Ross Study [1], Current Direct Replication Study, and Combined Data

Etiologies of VFI by categories, i.e., iatrogenic, idiopathic, neurological, and trauma, for the current study are listed in Table 2. Consistent with the original and combined data, the same etiologies were more strongly associated with side of VFI. Left VFI occurred most frequently due to surgical trauma. Specifically, cardiac surgery and esophageal surgery were associated with left VFI in 100% (13/13) and 75% (8/12) of participants, respectively. Head and neck surgery (including thyroid surgery) was less associated with left VFI in 39% (10/26) of participants. Medical, neurosurgical, neurological, and trauma were not associated with side of VFI.

Bolus Flow Characteristics from the Original Leder and Ross Study [1], Current Direct Replication Study, and Combined Data

Table 3 shows incidences of bolus flow before the pharyngeal swallow, bolus retention after the pharyngeal swallow, and laryngeal penetration for both liquid and puree bolus consistencies in participants who aspirated in the current study. Liquids were aspirated more frequently than puree. Signs of pharyngeal dysphagia were more prevalent with liquid versus puree bolus consistencies, and many patients exhibited more than one sign, i.e., liquid bolus retention (80%) and/or laryngeal penetration of (80%) versus puree bolus retention (78%) and/or laryngeal penetration (67%). The original study and combined data are in agreement with the present study and showed consistent patterns for bolus flow, bolus retention, and laryngeal penetration for both liquid and puree consistencies.

Aspiration Status and Side of VFI from the Original Leder and Ross Study [1], Current Direct Replication Study, and Combined Data

Table 4 gives the aspiration status for the current study based on age and side of VFI, i.e., right, left, or bilateral. Data indicated that 42% (13/31) of participants with

Table 2 Categories of vocal fold immobility

	Leder and Ross (2005)	Present study	Combined data
Iatrogenic	$N = 48/81$ (59.3%)	$N = 62/112$ (55.4%)	$N = 110/193$ (57.0%)
Cardiothoracic surgery	14/48 (29.2%)	13/62 (20.9%)	27/110 (24.5%)
Esophageal surgery	13/48 (27.1%)	12/62 (19.4%)	25/110 (22.7%)
Head/neck surgery	13/48 (27.1%)	26/62 (41.9%)	39/110 (35.5%)
Neurosurgery	8/48 (16.7%)	11/62 (17.7%)	19/110 (17.3%)
Idiopathic	$N = 22/81$ (27.2%)	$N = 40/112$ (35.7%)	$N = 62/193$ (32.1%)
Medical	9/22 (40.9%)	9/40 (22.5%)	18/62 (29.0%)
Pulmonary	4/22 (18.2%)	9/40 (22.5%)	13/62 (21.0%)
Metastatic breast cancer	3/22 (13.6%)	15/40 (37.5%)	18/62 (29.0%)
Other	6/22 (27.3%)	7/40 (17.5%)	13/62 (21.0%)
Neurological	$N = 6/81$ (7.4%)	$N = 6/112$ (9.8%)	$N = 12/193$ (6.2%)
Stroke	5/6 (83.3%)	5/6 (83.3%)	10/12 (83.3%)
Parkinson's disease	1/6 (16.7%)	1/6 (16.7%)	2/12 (16.7%)
Trauma	$N = 5/81$ (6.2%)	$N = 5/112$ (4.5%)	$N = 10/193$ (5.2%)
Motor vehicle crash	5/5 (100%)	5/5 (100%)	10/10 (100.0%)

Table 3 Incidences of bolus flow, bolus retention, and laryngeal penetration with liquid and puree bolus consistencies in participants who aspirated ($n = 36$ [Leder and Ross 2005]; $n = 45$ [present study]; $n = 81$ [combined data])

Leder and Ross (2005)			Present study			Combined data		
Bolus flow	Bolus retention	Laryngeal pen.	Bolus flow	Bolus retention	Laryngeal pen.	Bolus flow	Bolus retention	Laryngeal pen.
Liquid bolus consistency								
3/36 (8%)	31/36 (86%)	19/36 (53%)	3/45 (7%)	36/45 (80%)	36/45 (80%)	6/81 (7%)	67/81 (83%)	55/81 (68%)
Puree bolus consistency								
3/36 (8%)	21/36 (58%)	17/36 (47%)	3/45 (7%)	35/45 (78%)	30/45 (67%)	6/81 (7%)	56/81 (69%)	47/81 (58%)

Many participants exhibited more than one sign of pharyngeal dysphagia associated with aspiration, e.g., bolus retention and laryngeal penetration

Table 4 Aspiration status based on age and side of vocal fold immobility, i.e., right, left, or bilateral

Vocal fold immobility	Leder and Ross (2005)			Present study			Combined data		
	Right ($N = 25$)	Left ($N = 49$)	Bilateral ($N = 7$)	Right ($N = 31$)	Left ($N = 65$)	Bilateral ($N = 16$)	Right ($N = 56$)	Left ($N = 114$)	Bilateral ($N = 23$)
Age (years)									
Mean	62.5	64.3	68.8	62.4	63.0	64.2	62.5	63.6	66.5
Range	41–80	17–89	59–80	35–91	29–92	17–92	35–91	17–92	17–92
Aspiration (%)	44 ($N = 11$)	43 ($N = 21$)	57 ($N = 4$)	42 ($N = 13$)	37 ($N = 24$)	50 ($N = 8$)	43 ($N = 24$)	40 ($N = 45$)	52 ($N = 12$)

unilateral right, 37% (24/65) of participants with unilateral left, and 50% (8/16) of participants with bilateral VFI aspirated. Mean ages based on aspiration status for unilateral right, unilateral left, and bilateral VFI were 62.4, 63.0, and 64.2 years, respectively. Consistent with the original and combined data, the present study found no differences in aspiration status due to age or side of VFI.

Discussion

Combining results from the current direct replication study ($n = 2,650$) with the original Leder and Ross report [1] ($n = 1,452$) permitted analysis of the largest data set in the literature dealing with VFI and dysphagia (total sample size of 4,102) and achievement of an important goal,

i.e., verification of facts from previous research [6]. Both the incidence of VFI (right, left, or bilateral) and the incidence of aspiration were confirmed at 4.7 and 24.5%, respectively. Combined results agreed with those of previous research by corroborating that an individual with VFI had 2.50 times the odds of aspirating as someone without VFI (95% CI = 1.86–3.37). Specifically, for liquid aspiration, OR = 2.41 (95% CI = 1.77–3.28), and for puree aspiration, OR = 2.08 (95% CI = 1.47–2.93). All other outcome measures were corroborated as well, i.e., left VFI occurred most frequently due to surgical trauma, liquid was aspirated more often than a puree [14], VFI was exhibited more often in males versus females, while age and side of VFI (right, left, or bilateral) were again found not to be factors that increased incidence of aspiration.

FEES, being a mature evaluation technique that allows for both the diagnosis of pharyngeal dysphagia and the implementation of appropriate rehabilitation interventions with the goal of promoting safe and efficient swallowing, is ideally suited to evaluate laryngeal physiology and determine etiology of pharyngeal dysphagia based on bolus flow characteristics [15]. Recent research compared FEES with videofluoroscopic swallowing evaluation and reported that FEES had greater sensitivity and specificity in detecting the critical variables of delay in triggering the swallow reflex, pharyngeal residue after the swallow, and laryngeal penetration and tracheal aspiration of various consistencies of foods and liquid [16, 17].

Overall incidence of VFI remained high at approximately 5% from the start of the original study (December 1999) to the completion of the current direct replication study (December 2007). The end result was the identification of almost 200 new patients with VFI who would not otherwise have been diagnosed if they had been evaluated with videofluoroscopy, underscoring the importance of performing FEES with at-risk patients referred for dysphagia testing.

Speech-language pathology identified VFI, determined oral feeding status, and made appropriate recommendations to promote safe swallowing. Otolaryngology was consulted for further evaluation and treatment of laryngeal pathology, thereby reinforcing the importance of team treatment and fostering both professional collegiality and timely patient care. It is predicted that due to multiple factors, e.g., the aging population, advances in cardiac surgery, and improved cancer survival rates, both the incidence of VFI and the associated pharyngeal dysphagia and aspiration will not only continue but will increase in the future [18].

It is important to emphasize that aspiration does not always occur in the presence of VFI and, conversely, aspiration can occur when the true vocal folds are functioning normally [1], i.e., in the combined data set, 58% of participants with VFI swallowed successfully. The relationship among pharyngeal dysphagia, aspiration, and laryngeal functioning is more complex than simply impaired glottic closure during swallowing [19–21]. Pharyngeal dysphagia resulting in aspiration will occur only when the pharyngeal swallow is altered enough to prevent efficient bolus passage from the oral cavity through the pharynx and into the esophagus. Patients with unilateral tenth nerve palsy and isolated recurrent laryngeal nerve injury not only demonstrate ipsilateral VFI but exhibit supraglottic laryngeal and pharyngeal abnormalities capable of causing aspiration independent of VFI status, e.g., reduced laryngeal elevation, weak pharyngeal stripping wave, and pharyngeal retention [19, 20, 22]. VFI, therefore, may not be the single or even the most important factor contributing to pharyngeal dysphagia and aspiration, but rather may be one of a number of potential variables.

Study Strengths, Limitations, and Future Research

The major strengths of this study that promoted generalizability were a consecutively accrued, large, and heterogeneous population sample with a wide variety of diagnostic categories, and, most importantly, confirmation of previous results [1]. Limitations of this study were use of a referred case series rather than a randomized design and nonblinded rater reliability of VFI status. Future research is needed to investigate VFI from different clinical environments, i.e., outpatient settings, different referral sources, i.e., not only for dysphagia testing, and longitudinal follow-up to determine rate of VFI resolution.

Conclusion

In the acute-care setting, vocal fold immobility, with an incidence of 5.6% in the original study (n = 1,452), 4.3% in the direct replication study (n = 2,650), and 4.7% in the combined data set (n = 4,102), is not an uncommon finding when evaluating a referred population for dysphagia. Aspiration occurred with an incidence of 29.3% in the original study, 21.9% in the direct replication study, and 24.5% in the combined referral population. When VFI was present, aspiration increased by 15% in the original study, 18% in the direct replication study, and 17% in the combined study. Overall, an individual with VFI had 2.50 times the odds of aspirating as someone without (95% CI = 1.86–3.37). Specifically, for liquid aspiration OR = 2.41 (95% CI = 1.77–3.28), and for puree aspiration, OR = 2.08 (95% CI = 1.47–2.93). There were no inconsistent results noted among the original, direct replication, and combined data sets, i.e., left VFI occurred most frequently due to surgical trauma, a liquid bolus was aspirated more often than a puree bolus, and both side of VFI (left, right,

or bilateral) and age were not factors associated with an increased incidence of aspiration. Both VFI and dysphagia will likely increase in the future due to an aging population, advances in cardiac surgery, and improved cancer survival rates.

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