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A pre- and post-operative protocol for assessment of voice and swallowing function in patients undergoing heart or lung transplantation

Rebecca Black, BApSc, Speech Pathologist(SP),[a,b,1,2,*]
Duy Duong Nguyen, MD PhD,[b,d,3] Anna Miles, PhD,[c,4]
Daniel Novakovic, MBBS, FRACS, MPH,[b,5]
Marshall Plit, Prof., MBBS, FRACP, PhD,[a,6]
Peter MacDonald, Prof. MBBS, FRACP, PhD, MD, FCANZ,[a,7] and
Catherine Madill, BAppSc (SP), BA, PhD[b,8]

[a]*St Vincent's Hospital, Darlinghurst, Australia*
[b]*Voice Research Lab, Faculty of Medicine and Health, The University of Sydney, Sydney, Australia*
[c]*Speech Science, The University of Auckland, New Zealand*
[d]*National Hospital of Otorhinolaryngology, Hanoi, Vietnam*

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BACKGROUND: Oropharyngeal dysphagia and laryngeal dysfunction are complications of lung and heart transplantation. However, there is a lack of understanding around pre-operative function and an absence of standardized assessment protocols. We aimed to trial a pre- and post-operative protocol for assessing voice and swallowing function.

METHOD: A prospective, longitudinal study of 14 adults undergoing investigation for lung or heart transplantation was conducted at a tertiary referral hospital. Patients were assessed pre-surgery and up to 6 months afterwards. The protocol involved phonation tasks with auditory-perceptual and acoustic

Abbreviations: ADSV, Analysis of Dysphonia in Speech & Voice; CAPE-V, Consensus Auditory-Perceptual Evaluation of Voice; CLAD, Chronic Lung Allograft Dysfunction; CSID, Cepstral Spectral Index of Dysphonia; PROMS, Patient Reported Outcome Measures; EAT-10, Eating Assessment Tool −10; FEES, Flexible Endoscopic Evaluation of Swallowing; FOIS, Functional Oral Intake Scale; GFI, Glottal Function Index; IDDSI, International Dysphagia Diet Standardization Initiative; LAR, Laryngeal Adductor Reflex; LPD, Laryngopharyngeal Dysfunction; PAS, Penetration Aspiration Scale; PRAAT, Phonetic and Acoustic Analysis Tool kit; VFP, Vocal Fold Palsy; VF, Vocal Fold; OPD, Oropharyngeal Dysphagia; SLP, Speech Language Pathologist; VoiSS, Voice Symptom Scale

*Corresponding author: Rebecca Black, St Vincent's Hospital, Darlinghurst, NSW 2010, Australia.Telephone: +44-61 431997112
E-mail address: theblacks27@gmail.com.
[1] https://orcid.org/0000–0002-4691–0697
[2] Reprint requests
[3] https://orcid.org/0000–0001-8097–8938
[4] https://orcid.org/0000–0003-3260–5824
[5] https://orcid.org/0000–0003-3839–1353
[6] https://orcid.org/0000–0001-8742–1745
[7] https://orcid.org/0000–0001-5378–2825
[8] https://orcid.org/0000–0001-8114–1427

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analysis, videolaryngostroboscopy, a flexible endoscopic examination of swallowing and patient reported quality of life measures. Risk factors and clinical outcomes were extracted from patient records.
RESULTS: Patient self-reports of swallowing and voice difficulties were elevated pre-operatively. No evidence of swallowing difficulty was observed under endoscopic examination pre-transplant (Penetration-Aspiration Scale score < 2; no accumulated secretions) and only one patient presented with incomplete glottic closure. Auditory perceptual ratings revealed voices were largely within the healthy range at baseline. One out of five patients presented with severe dysphonia post-operatively. Completion of evaluation measures prior to transplantation was 79% but post- operative rates were low due to feasibility challenges with follow up in this complex population.
CONCLUSION: Novel evidence of self-reported pre-transplant voice and swallowing changes indicate value in baseline screening. Discrepancies between patient-report and instrumental assessment results highlight the need for multi-faceted evaluation. Large cohort studies are needed to determine the salient evaluation measures and time points for voice and swallowing assessment in this population.
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Introduction

Heart and/or lung transplantation is the definitive treatment to prolong life for those with end stage heart and/or lung failure who have exhausted medical management options.[1–3] Advancements in surgical techniques and innovations in immunosuppressive medications over the past two decades have resulted in improved clinical success. However, survival remains inferior to other solid organ transplants.[1,3] Hence, the impact of complications, such as primary graft failure, multi organ failure and infection, on morbidity and mortality has become a strong area of focus within cardiothoracic transplantation services.

Dysphagia and resultant aspiration is known to be significantly associated with increased morbidity and mortality in a range of patient populations.[4–6] To date, literature surrounding aspiration in the cardiothoracic transplant population has been largely focussed on esophageal dysmotility and gastroesophageal reflux disease (GERD) with the inherent risk of retrograde flow of digested materials into the lungs.[7–9] However, recent reports suggest that laryngopharyngeal dysfunction (LPD), defined as oropharyngeal dysphagia (OPD) and laryngeal dysfunction can occur after transplantation for a variety of reasons including medical, surgical, polypharmacy, respiratory and patient related factors.[10–13] Although current literature is scant, there is an alarmingly high incidence of OPD reported, with findings ranging from 40–75% in patients following lung transplantation,[10,14–16] and compromised airway patency, due to vocal fold palsy, with rates of up to 34%.[14,15,17] Silent aspiration, defined as entry of food, fluid or secretions through the glottis into the bronchotracheal system without the elicitation of a cough reflex, is reported to be present in up to 75% of patients with OPD following lung transplantation,[14,15,18] indicating serious concerns for compromised respiratory function and the need for objective assessment of swallowing.[13] The potential for aspiration-related pulmonary complications in this immunocompromised population is supported by emerging evidence of aspiration as a contributing factor in chronic lung allograft dysfunction (CLAD),[19] the most common leading cause of death, alongside infection, within 1–5 years after lung transplantation.[1]

Given the consistently high rates of OPD, particularly silent aspiration, and risk of vocal fold palsy (VFP) following transplantation, routine investigation of laryngopharyngeal function post-operatively is supported by existing data. However, there is an emerging theme in the literature surrounding our gap in understanding of swallowing and vocal function in those awaiting transplantation and the lack of standardized protocols for assessment.[13,20] Although baseline variability exists amongst those awaiting transplantation, frailty and severely compromised respiratory function are common and are associated with an increased risk of dysphagia.[21–24] The lack of baseline data regarding voice and swallowing function in this field is potentially related to the inherent variation in transplantation workup protocols across centers.

To our knowledge, the only available prospective study to investigate pre-operative swallowing function[11] demonstrated pre-existing dysphagia to be low in a cohort of patients undergoing lung transplantation. However, laryngeal function via laryngoscopy was not reported and hence airway patency is unknown. There is also a lack of data regarding the impact of LPD on quality of life.

The absence of robust prospective data reporting on baseline function has major implications for the patient, the multidisciplinary team and service providers. If pre-operative assessment identifies dysfunction in vocal fold mobility and/or swallowing function prior to surgery, this may enable surgeons to take additional care when approaching the Recurrent Laryngeal Nerve (RLN) and allow for patient education regarding the potential surgical risk. In addition, post operative intervention could be expedited to avoid further complications. However, laryngeal examination and objective swallowing assessment via Flexible Endoscopic Evaluation of Swallowing (FEES) may cause discomfort for the patient and increase medical costs, so their inclusion

as standard practice must be justified by robust data to confirm that the benefits outweigh the costs. Pre-transplant function data is also necessary to enable patient education regarding the true incidence of post-operative dysphagia and laryngeal dysfunction and whether signs of pre-operative LPD may be predictive of increased post operative symptoms. Moreover, there is a significant absence of guidelines for healthcare providers regarding the best practices for allocating Speech Language Pathology (SLP) services. This includes guidelines on which assessments should be administered to investigate voice and swallowing function, when to conduct them and the potential benefits of these evaluations for patient care.

Hence, the aims of this study were: (1) to design and trial an assessment protocol for the comprehensive evaluation of voice and swallowing function prior to and following transplantation and examine its value and feasibility; and (2) to investigate patients' voice and swallowing function, and other related co-morbidities, prior to transplantation.

Methodology

A single site prospective repeated-measures, longitudinal study was conducted at a tertiary referral center between May 2021 and August 2023. Local site ethics approval was gained and all patients provided written consent to participate (2019/ETH00246).

Participants

Inclusion criteria were: (1) ≥18 years of age, (2) medically well enough at the time of the study to complete the pre-operative assessment and (3) able to read and understand the participant information sheet and provide written consent. Patients were excluded from the study if they had a: (1) past history of heart or lung transplantation, (2) known existing voice or swallowing disorder unrelated to their reason for transplantation listing (3) inability to tolerate transnasal flexible laryngoscopy and/or (4) known language and/or cognitive impairment.

Fourteen patients were recruited either randomly from the transplantation workup clinic lists, or referred by the transplant co-ordinators, based on the patient's history of compliance with the workup procedure. Demographics, pre-operative risk factors and post operative variables were extracted from clinical records by the principal investigator.

Assessment protocol

In the absence of a published protocol for comprehensive assessment of voice, laryngeal and swallowing function for pre-and post-operative use in this population, the authors designed a protocol a priori. Selection of measures was based on multidisciplinary clinician expertise regarding standard clinical practice in swallowing and voice assessment. The assessment battery was conducted during the transplantation workup phase and then repeated at up to 4 points following transplantation (point 1: 72 hours post extubation, point 2:3 weeks, point 3: 9 weeks & point 4: 5 - 6 months post extubation). Self-assessment measures were not included at the first post-operative time point due to patient acuity. Time points were required to be flexible depending on patient health status and availability at the time of assessment. Feasibility of the study was assessed retrospectively.

The protocol included vocal function assessment using auditory-perceptual rating of recordings of a standard reading passage and prolonged vowel using the Consensus Auditory Perceptual Evaluation – Voice (CAPE-V), acoustic analysis, videolaryngostroboscopy and swallowing function assessment using FEES. Blinded voice and swallowing ratings were conducted by a trained SLP and videolaryngostroboscopy results were reviewed by a laryngologist. The detailed protocol can be viewed in the supplemental material.

Statistical methods

Data was managed in Microsoft Excel 365 and analysed using SPSS version 28 for Windows. Descriptive statistics were used to describe the cohort characteristics. For continuous variables, data were checked for normality. If normally distributed, population parameters were calculated including mean, standard deviation (SD) and 95% confidence interval. If the data was not normal, median, min-max, and quartiles were used. Binomial variables were analysed using frequency. Intra and inter-rater reliability for the auditory perceptual ratings of voice quality were calculated using intra-class correlation coefficients (ICC), two-way mixed model, consistency type, and single measure analysis [ICC(3,1)]. To assess the level of correlation, ICC < 0.5 indicated poor correlation, 0.5 - 0.75 moderate, 0.75 - 0.9 good, and > 0.9 excellent correlation.[25] Due to the small sample size of repeated measures, a single ICC value was calculated for intra-rater reliability from four of the voice parameters (Overall Severity, Roughness, Breathiness and Strain). Feasibility of the protocol was retrospectively measured via: (1) Retention rates and (2) Percentage completion of evaluation measures at each time point.[26]

Results

Of the fourteen participants who underwent baseline assessment during their transplant workup (mean age - 51.86 years (12.8), range (23–63)), five went on to receive a transplant during the data collection period. At the time of data analysis, eight patients remained on the waiting list and one patient was deemed ineligible for transplantation. Figure 1 depicts the flowchart of the study cohort. Characteristics of the study cohort are listed in Table 1. No patients presented with a history of aortic disease, cerebrovascular disease, stroke, dialysis, lymphoma or solid tumors, AIDS, liver disease, leukemia, dementia, or laryngeal surgery.

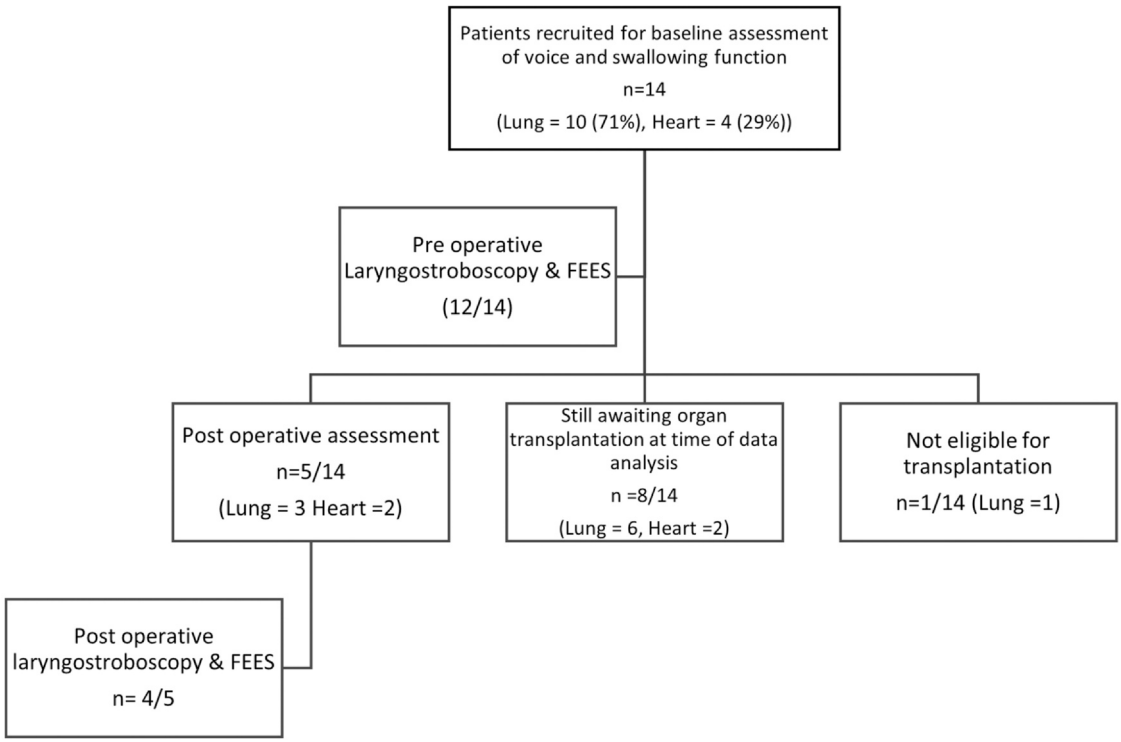

Figure 1 Flowchart of study cohort.

Voice and laryngeal function at baseline

Auditory perceptual assessment

CAPE-V results revealed the median score for all voice quality parameters to be 10 or below, indicating the vast majority of patients to be rated between normal voice and mild dysphonia (see Table 2).[27] Intra-rater reliability was excellent for both raters (rater 1: ICC single measure =.987 (.968–.995), p= ≤.001 and rater 2: ICC single measure.881 (.724–.951), p=≤.001) indicating a high level of consistency in repeated CAPE-V ratings by the same rater. Inter-rater reliability varied from moderate to good for all parameters except strain.[27] See Table 3 for inter-rater reliability measures.

Acoustic analyses

Signal typing revealed 13/14 of the baseline samples to be Type 1 or Type 2 (see $FigS_1$ in supplementary file). The remaining sample was type 4 and hence was not suitable for acoustic analysis.[28] In addition, the signal to noise ratio of four of the baseline samples was below 30 dB rendering them unsuitable for acoustic analysis.[29] Table 4 displays acoustic analysis data by patient. All patients scored a Cepstral Spectral Index of Dysphonia (CSID) value below 19 indicating normal or near normal voice quality at baseline.[30]

Videolaryngostroboscopy

Video footage was obtained for 12/14 patients pre-operatively. The predominant clinical features were false vocal fold hyperfunction and supraglottic constriction which were evident in ≥ 50% of patients. Incomplete glottic closure was only apparent for 1/12 patients. There was no evidence of pre-operative VFP (see Table 5).

Patient reported outcome measures (PROM's)

Patient self-report revealed mean scores to be in the pathological range in regard to vocal function post-operatively. 'Speaking takes extra effort' was the most commonly reported symptom (9/14) on the Glottal Function Index (GFI) and 'people fail to hear me when talking in company' was an issue to varying degrees for 13/14 patients as reported on the Voice Symptom Scale (VoiSS) (See Table S1 in supplementary file for PROMS results and normative cut off values from the literature).

Swallowing function at baseline

FEES

There was no evidence of dysphagia on FEES prior to transplantation, as evidenced by no occurrences of aspiration and 100% of patients having a Penetration Aspiration

Table 1 Baseline characteristics of the study population (n=14)

Variable	Number of Patients (%)
Gender	
Male	6 (42.9%)
Female	8 (57.1%)
Type of transplant required	
Bilateral Lung	10 (71.6%)
Heart	4 (28.4%)
Pre-operative oxygen support	4/14 (28.4%)
Medical history	
Past history of smoking	6 (42.9%)
Diabetes	2 (14.3%)
Connective tissue disorder	2 (14.3%)
GERD	5 (35.7%)
Respiratory disease	8 (57.1%)
Hypertension	4 (28.4%)
Asthma	4 (28.4%)
Thyroid disease	2 (14.3%)
Myocardial infarction	1 (7.1%)
Hypercholesterolemia	1 (7.1%)
Renal failure	1 (7.1%)
Neurological disease	1 (7.1%)
Primary reason for lung transplant	
COPD	4 (28.4%)
Interstitial lung disease	2 (14.3%)
Sarcoidosis	1 (7.1%)
Congenital pulmonary fibrosis	1 (7.1%)
Idiopathic lung disease	1 (7.1%)
Pulmonary lymphangioleiomyomatosis	1 (7.1%)
Primary reason for heart transplant	
Congenital heart disease	1 (7.1%)
Ischemic cardiomyopathy	1 (7.1%)
Non ischemic cardiomyopathy	1 (7.1%)
Idiopathic dilated cardiomyopathy	1 (7.1%)

GERD: Gastroesophageal reflux disease, COPD: Chronic obstructive pulmonary disease

Table 2 Baseline auditory perceptual data for CAPE-V ratings (n=14). Measures calculated from two raters

Parameter	Median	Interquartile Range (IQR)	Minimum	Maximum
Overall severity	10	5–20.5	0	55
Roughness	10	7–20	0	62
Breathiness	8	2.25–15	0	44
Strain	10	7–16	0	72
Pitch	0	0	0	38
Loudness	0	0–10	0	43

Scale (PAS) score of 2 or below. Furthermore, palatal movement, base of tongue retraction and pharyngeal squeeze were normal and there was no report of pooled secretions. Ratings for residue in the valleculae and pyriform fossae were variable. For all parameters other than residue, inter-rater reliability was greater than 90%. Data for the laryngeal adductor reflex (LAR), tested via direct stimulation during videolaryngostroboscopy, was only obtained for 50% of patients at baseline. See Table 6 for FEES ratings.

Functional & patient reported outcome measures

At the time of workup for transplantation, all patients were on a full oral diet with scores of 7 for food and 0 for fluids on the International Dysphagia Diet Standardization Initiative (IDDSI) scale (0=normal fluids and 7=regular food textures). Two patients reported they needed to limit some foods on occasion due to difficulty in swallowing i.e. Functional Oral Intake Scale (FOIS) score of 6 or above.

Self-assessment scores were within the pathological range for 50% of patients (See Sup1 in supplementary file for PROMS results and normative cut off values from the literature). The most frequently reported issue by patients on the Eating Assessment Tool (EAT-10) was 'swallowing solids takes extra effort' (7/14), followed by 'the pleasure of eating is affected by my swallowing' (6/14) (See Table S1).

Protocol feasibility & post-operative results

Once enrolled, no patients requested to withdraw from the study. Completion of evaluation measurements at baseline was between 79%–100%. One patient was unable to tolerate the pre-operative laryngoscopy/FEES procedure, but did not wish to withdraw from the study, and another requested to delay a post-operative laryngoscopy/FEES as he did not feel well enough to comply at that time point. There were no other instances of refusal of any evaluation measures. Collection of data for the LAR was affected by its placement at the end of the protocol to avoid the impact of potential laryngospasm on the subsequent oral trials. No episodes of laryngospasm occurred, however patients frequently requested the endoscope be removed immediately after oral trials and/or the endoscopist neglected to recall the need to assess the LAR at this point.

Post operative completion rates were low due to logistical challenges of accessing patients on the hospital ward and in an outpatient capacity at suitable time points and lack of dedicated staffing resources. Completeness of evaluation measures at each time point can be seen in Table 7. Five patients had follow-up assessment after transplantation and are reported here as a case series; 4/5 underwent videolaryngostroboscopy and FEES post-operatively (see Table S2 in supplementary file for postoperative risk factors).

Auditory perceptual ratings

Auditory perceptual ratings for those who underwent transplantation revealed little change for Subjects 1, 12 and 9 with scores remaining within normal range (20 or below) for all measures. However, Subjects 4 and 8 increased from scores within normal range to between moderate to severe

Table 3 Inter rater reliability for CAPE-V auditory perceptual ratings for all pre and post-operative measures

Parameter	Measures	ICC (95% CI)	*p*
Overall severity	Single measure	.768 (.502 –.901)	≤.001*
	Average measure	.869 (.668–.948)	≤.001*
Roughness	Single measure	.621 (.257 -. 830)	.001*
	Average measure	.766 (.408 –.907)	.001*
Breathiness	Single measure	.603 (.231 –.822)	.002*
	Average measure	.752 (.375 –.902)	.002*
Strain	Single measure	.284 (–.170 –.638)	.106
	Average measure	.442 (–.409 –.779)	.106

ICC = Intraclass correlation coefficient, *= statistically significant

Table 4 Acoustic data at baseline

Patient ID	Signal Type	HNR Vowel (dB)	LH Vowel (dB)	F0 of RP (Hz)	CPP Vowel (dB) (ADSV)	CPP Vowel (dB) (PRAAT)	CPP RP (dB) (ADSV)	CPP RP (dB) (PRAAT)	CSID Vowel	CSID RP
S1	1	29.0	41.8	130.6	14.2	18.4	6.2	8.2	–7.0	–6.0
S2	2	17.7	42.8	145.2	9.5	13.2	6.0	7.7.	28.9	4.3
S3	2	21.9	28.1	183.2	14.7	21.3	5.1	7.6	12.8	19.3
S6	2	23.6	30.6	195.8	12.1	46	6.0	8.6	–0.7	16.3
S7	2	21.9	36.3	204	9.85	13.6	5.4	8.2	28.7	13.5
S9	2	24.3	33.4	224.3	12.7	15.2	5.7	8.7	–3.9	10.3
S10	2	26.8	43.6	180.8	14.8	19.5	6.4	9.4	–20.8	–0.2
S12	2	23.0	44.6	129.6	14.6	14.5	6.5	8.7	–7.0	–4.9
S13	2	25.9	44.4	167.6	12.2	15.7	5.5	8.6	4.6	7.1

Baseline voice samples for S4, S5, S8 and S11 voice were not suitable for analysis due to signal to noise ratio below 30 dB. S14 baseline was not analysed due to poor signal type. For all vowel tasks, the average of 3 measures is reported.

HNR: harmonics to noise ratio, Max: maximum, F0: fundamental frequency, RP: rainbow passage, CPP: Cepstral Peak Prominence, ADSV: Analysis of Dysphonia in Speech and Voice, CSID: Cepstral Spectral Index of Dysphonia.

dysfunction for roughness, breathiness, loudness and strain (51–75)[27] (see Figure 2).

Acoustic analyses

Signal typing revealed only two patients to have voice samples that were suitable for acoustic analysis after transplantation. The CSID for the rainbow passage for both of these patients increased in comparison to their baseline measures. Subject 1 CSID increased from –6.0 to 16.9, however this score remained in the normal voice range while subject 9 increased from 10.3 to 24.39 putting them in the mild to moderate voice disorder range.[30]

Videolaryngostroboscopy

Pre and post-operative stroboscopy comparison data were available for only three patients. S4 showed changes in AP constriction (present at baseline and absent post-operatively); S8 showed pre and post-operative differences in gross VF movement, glottal closure, phase closure, and false vocal fold hyperfunction with diagnosis of a right VF palsy. Meanwhile, S9 only showed changes in abduction lag (present at baseline and absent post-operatively).

Swallowing

Both raters reported a Penetration Aspiration Scale (PAS) of 1 (indicating no material entered the airway) for 3/4 patients. Rating of aspiration for the remaining patient was inconsistent between the raters with one rater reporting a PAS of 8 whilst the other logged a rating of 1. A third rater was sought and consensus was reached that there was no aspiration evident (PAS ≤2 reported).

Discussion

Compromised laryngopharyngeal function and associated pulmonary complications can present a significant risk to the immunosuppressed patient following heart or lung transplantation. However, current practice for investigation of LPD in many heart/lung transplant centers does not follow a standardized protocol.[20] In addition, referral for SLP assessment may only be prompted by overt symptoms of dysfunction or patient request. Recent studies suggest that this process requires reform and that a standardized protocol, inclusive of pre-operative assessment, should be conducted for all patients.[13,20] The precipitating factors for

Table 5 Characteristics of vocal function on videolaryngostroboscopy for 12/14 patients at baseline

Parameters	Ratings	Number of VF Stroboscopy Activities at Baseline
Gross VF movement (* counted on both VF's)	Normal	19
	Decreased	5
	Absent	0
Abduction lag	No	8
	Yes	4
Mucosal wave glottic closure	Complete	10
	Irregular	1
	Incomplete	1
Mucosal wave phase symmetry (* counted on both VF's)	In phase	14
	Out of phase	2
	N/A	8
Mucosal wave phase closure (*counted on both VF's)	Normal	18
	Open phase	2
	N/A	4
Amplitude (*counted on both VF's)	Normal	18
	Decreased	1
	N/A	5
Periodicity (*counted on both VF's)	Regular	18
	Irregular	2
	N/A	4
False vocal fold hyperfunction (*counted on both VF's)	None	12
	L or R	12
Supraglottic lateral constriction	No	5
	Yes	7
Supraglottic AP constriction	No	5
	Yes	7

VF: vocal fold, *: these parameters are measured on both vocal folds (n=12 x2 VF's =24)

voice and swallowing complications in this population requires more extensive evaluation, however the pathophysiology is known to be multifactorial.[12] As a result, any proposed protocol needs to be adequately comprehensive to account for this complexity. In addition, objective assessment of both swallowing and laryngeal function is required due to the known high rates of silent aspiration which may otherwise go undetected. An optimal standardized assessment methodology would identify potential risk factors in order to enable early intervention and avoid adverse outcomes such as aspiration, allow targeted education about the inherent operative risks[14,31] and inform best practice service provision.

To our knowledge, this is the first prospective study to trial a novel protocol for assessment of voice and swallowing function in this population prior to and following transplantation with the inclusion of patient reported measures and gold standard endoscopic evaluation.

Assessment of voice and laryngeal function

The comprehensive voice assessment outlined in our protocol includes voice recordings with both acoustic analysis and auditory perceptual ratings, as well as patient self-assessment. Self-report scores from both the VoiSS and the GFI demonstrated high rates of voice disorder at baseline which has not been previously reported in this cohort. This is not surprising given over 70% of the study population had a diagnosis of severe respiratory disease, known to be affiliated with voice changes for a variety of reasons, including changes to the glottic mechanism and laryngeal airflow, and medication effects.[32,33] However, variation existed between patient self-report and formal evaluation measures with auditory perceptual ratings and acoustic analysis data indicating most patients presented with largely healthy voices. Interpretation of this discrepancy would require larger sample sizes, however, our results reveal valuable information about the importance of including patient self-report in any protocol for voice assessment, rather than solely relying on clinician investigation. This will ensure a greater depth of understanding of function.

Table 6 FEES results at baseline

		Pre-operative n=12		
Parameters	Rating	Rater 1	Rater 2	Inter Rater Agreement
Palatal movement	Adequate	11	12	92%
	Reduced	1	0	
	Absent	0	0	
New Zealand Secretion Scale (NZSS) total (max = 7)	Less than 1	12	12	100%
Base of tongue retraction	Adequate	12	12	100%
Pharyngeal squeeze	Yes	12	12	100%
	No	0	0	100%
Aspiration	Yes	0	0	100%
	No	12	12	100%
Silent airway invasion	Yes	0	0	100%
	No	12	12	100%
Penetration Aspiration Scale (PAS)	2 or below	12	12	100%

Table 7 Completion of evaluation measures at baseline and post operative time points

	Baseline (n=14)	Post-op (n=5)			
Evaluation Measure		Point 1	Point 2	Point 3	Point 4
Eating Assessment Tool–10	14 (100%)	N/A	2 (40%)	1 (20%)	*
VoiSS	13 (93%)	N/A	2(40%)	1 (20%)	*
GFI	14 (100%)	N/A	2 (40%)	1 (20%)	*
Functional swallowing rating scales - FOIS and IDDSI	14 (100%)	3 (60%)	1 (20%)	*	*
Phonation tasks	14 (100%)	3 (60%)	2 (40%)	*	*
Videolaryngostroboscopy & FEES	11 (79%)	3 (60%)	2 (40%)	*	*

*= Missing data points: lost to follow up. VoiSS: voice symptom scale, FOIS: functional oral intake scale, IDDSI: International Dysphagia Diet Standardization Initiative, FEES: flexible endoscopic evaluation of swallowing,

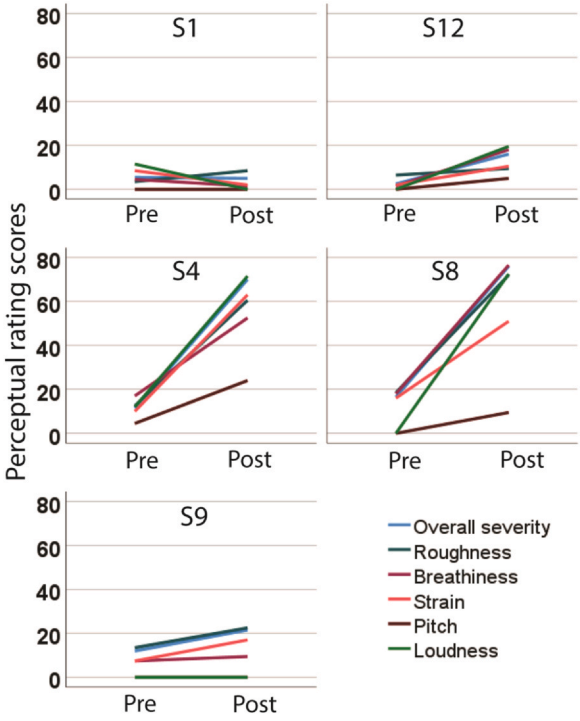

Figure 2 Comparison of baseline and post operative CAPE-V auditory perceptual ratings for 5/5 patients who underwent transplantation.

Acoustic analysis of post-operative recordings in the ward environment proved untenable for this cohort due to the impact of high ambient noise levels on the sample quality. It was also challenging for the post-operative patient to produce all standardized vocal tasks given their physical status after transplantation. Alternatively, auditory perceptual ratings, such as the CAPE-V rating tool were simple to collect at the bedside and hence may prove a more practical measure to conduct in the first instance. Further investigation is required to determine at which time points these tools should be administered and whether the results can be utilized to inform the potential need for more thorough voice analysis when the patient is adequately stable to access a quiet environment.

Should high level acoustic analysis be indicated, our results also suggest that the number of phonation tasks can be minimized. The sustained vowel task, used to determine maximum phonation time, and the Rainbow Passage were the most sensitive in detecting voice problems prior to transplantation. These findings are consistent with the literature regarding the effectiveness of maximum phonation time as a biomarker of disease.[33–35]

Future studies should investigate whether early changes in vocal function, as determined by self-assessment measures or formal analysis at baseline, are predictive of increased risk to the voice post-operatively. These results will inform which voice measures are an essential part of an assessment protocol.

Assessment of swallowing function

The absence of any significant pre-transplant swallowing dysfunction on objective assessment amongst our cohort supports the findings from recent retrospective studies where aspiration occurred infrequently in patients prior to lung transplantation.[16,36] In addition, only 1/12 patients were found to have incomplete glottic closure on vocal tasks and volitional cough testing during videolaryngostroboscopy. This indicates patent motor protection of the airway for the majority of patients. However, the fact that 57% of our cohort reported experiencing some swallowing issues, (in the lower end of the abnormal range), on pre-surgery self-assessment questionnaires adds new information to the evidence base for this population. Despite being able to tolerate a normal diet and fluids and normal FEES findings, patients' self-report of swallowing difficulties may reflect more subtle alterations in mealtime efficiency and enjoyment, possibly explained by the high proportion of patients with multiple comorbidities such as reflux, respiratory compromise and polypharmacy. Reflux and oropharyngeal dysphagia are known to co-exist[15] and respiratory compromise can disrupt co-ordination of the breath swallow cycle.[24,36,37] This is consistent with reports from our cohort regarding solids requiring more effort to eat and the pleasure of eating being affected. It is highly likely that these elevated EAT-10 scores reflect slow-onset swallowing difficulties that patients have sufficiently adapted and compensated for over time, to avoid airway compromise or need for diet modification. The variation between patient self-report and objective measures needs to be

further assessed within a large study cohort in order to enable interpretation, however it may suggest that our current assessment methods are not adequately sensitive to detect these subtle changes to function.

Our low rates of swallowing dysfunction post-operatively are in contrast with the existing literature,[10,14–16] however due to the small sample size, particularly the low number of patients who completed all post operative assessments, limited interpretation can be made from these results.

Although we were unable to obtain a full data set for testing of the glottic closure reflex via direct stimulation, we acknowledge that the inclusion of LAR testing and/or cough reflex assessment via standardized inhalation technique[16,38] could prove a clinically useful addition to the protocol. Such investigations allow for more direct testing of the sensorimotor cough reflex, which is primarily used for defence of the airway and is known to be associated with severe respiratory disease[39,40] and GERD.[41] The absence of a cough reflex may prove to be a potential risk of aspiration, indicating the need for early post operative intervention.

Results from this study support the current literature that severe swallowing dysfunction in heart/lung transplantation is likely to be of intra and/or postoperative etiology.[12] However, there is a clear indication of the value of baseline assessment of function given that patients may experience early changes in swallowing function that impact their quality of life and hence self-reported swallowing difficulties should not be dismissed. Studies with larger sample sizes are required to determine whether pre-operative routine swallowing assessment via FEES is of benefit to the patient and the multidisciplinary team. Alternatively, patient self-assessment measures may prove sufficient to indicate potential risk and the need for close monitoring following surgery.

Feasibility

High completion rates for assessment measures at baseline demonstrate patients' ability to comply with rigorous evaluation prior to transplantation, despite their co-morbidities. In addition, although not directly measured, 100% retention rate suggests that patients were engaged with the research team and understood the potential benefits of the study. However, our limited data for the post operative timepoints is reflective of the complexity of conducting real-world clinical research with patients who have had major surgery in the absence of dedicated staffing resources.

Limitations and suggestions for future studies

Despite obtaining a novel prospective data set for pre-operative swallowing and vocal function for those undergoing heart or lung transplantation, this study had several limitations. We acknowledge that there are a number of outstanding questions which require further investigation in order to determine which exact components of a voice and swallowing assessment protocol are the most salient to minimize risk and optimize post transplantation outcomes.

Our small sample size and incomplete post operative assessment data meant that only descriptive statistics could be reported and hence challenges the ability to generalize our findings. Future studies with larger sample sizes should also consider separate analysis of heart and lung transplantation data given the differing surgical complexity and associated risks. In addition, the cohort size did not enable us to determine whether elevated voice and swallowing measures were associated with increased LPD following transplantation. This evidence would support the potential need for early intervention for those considered to be at high risk.

Multiple factors contributed to lower enrollment numbers than was initially anticipated. The recruitment period for this study was impacted by extended COVID 19 lockdown periods which prevented in-person attendance at the heart lung clinic. In addition, the unpredictability of organ availability and timeframes to transplantation was apparent amongst our cohort, where over half of the patients recruited were still awaiting transplantation at the time that data collection was ceased. To combat this issue, we suggest that a longer recruitment period, larger enrollment numbers at baseline and adequate resources are required, including the capacity for repeat assessment while patients remain on the transplant list.

The comprehensive nature of the protocol, involving assessment prior to transplantation, and at multiple post operative time points, proved resource intensive. Longitudinal follow up was also problematic due to patients returning to their place of residence, often a great distance away, once medically stable. All of these factors had a direct impact on the robustness of the data collected.

Patients were not consecutively enrolled, and hence a selection bias towards those patients who agreed to being involved in the study cannot be excluded. It could be argued that patients who were more unwell prior to transplantation may not have been captured and so data may underestimate the existence of pre-operative dysfunction. However, we were able to ensure that rigorous, objective assessment of swallowing and laryngeal function was consistently conducted, and assessors of the data were blinded.

Conclusions

We have described an unprecedented protocol for the pre- and post-operative assessment of voice and swallowing function for lung and heart transplantation candidates, its feasibility and value and suggestions for protocol modifications. High patient retention rates and completion of baseline evaluation measures indicated the feasibility of the protocol prior to transplantation. Challenges were evident in longitudinal follow up with this critically ill population. Rates of self-reported swallowing difficulties and dysphonia were high in those awaiting transplantation, but

most patients presented with healthy voices, intact glottic closure and did not aspirate.

Our results have emphasized the need for a standardized assessment protocol. However, robust feasibility studies are now necessary to determine the exact voice and swallowing evaluation measures to be conducted at which time points in the transplant journey. This data would enable the burden of patient investigations to be minimized whilst reducing the risk of respiratory complications for this population and optimizing clinical resources. We recommend a multisite heart lung data repository with allocated and trained staff, as an efficient means of collecting adequate sample sizes. These data are essential to inform a clinical guideline for the optimal assessment protocol for voice and swallowing in this high-risk population.

Declaration of Competing Interest

The authors declare that they have no known competing financial interests or personal relationships that could have appeared to influence the work reported in this paper.

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Disclosure statement

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Appendix A. Supporting information

Supplemental data associated with this article can be found in the online version at doi:10.1016/j.jhlto.2025.100261.

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