Utility of Ultrasound in the Assessment of Swallowing & Laryngeal Function: A Rapid Review and Critical Appraisal of the Literature

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Abstract

Background Ultrasound is not widely utilised as part of the speech and language therapy (SLT) clinical toolkit. The COVID-19 pandemic has intensified interest in ultrasound as an alternative to SLT instrumental tools such as the videofluoroscopic swallowing study (VFSS), fibreoptic endoscopic evaluation of swallowing (FEES) and endoscopic evaluation of the larynx (EEL) as a non-invasive, non-aerosol generating procedure that can be delivered at the bedside to assess swallowing and/or laryngeal function. To establish the appropriacy of routine ultrasound use, and in response to a national professional body request for a position statement, a group of expert SLTs conducted a rapid review of the literature.

Aim To critically explore the clinical utility of ultrasound as an assessment tool for swallowing and laryngeal function in adults.

Methods A rapid review of four databases was completed to identify articles using ultrasound to assess swallowing and/or laryngeal function in adults compared to reference tests (VFSS/FEES/EEL/validated outcome measure). Screening was completed according to pre-defined inclusion/exclusion criteria and 10% of abstracts were re-screened to assess reliability. Data was extracted from full texts

using a pre-developed form. The QUADAS-2 tool was used for quality ratings. Information from included studies was summarised using narrative synthesis and visual illustration.

Main Contributions Ten papers utilised ultrasound to assess swallowing, and thirteen to assess laryngeal function. All were peer-reviewed primary studies across a range of clinical populations and with a wide geographical spread. Four papers had an overall low risk of bias, but the remaining 19 had at least one domain where risk of bias was judged high or unclear. Applicability concerns were identified in all papers. The papers that used ultrasound to assess swallowing varied widely in terms of anatomical structures assessed, and methodology employed. The papers assessing laryngeal function were more homogenous in their methodology. Sensitivity and specificity data were provided for 12 of the laryngeal function papers with a range of 64.3% -100% and 48.5%-100%.

Conclusions There is burgeoning evidence to support the use of ultrasound as an adjunct to SLT clinical assessment of swallowing and laryngeal function. However, the current literature does not support its use as a tool in isolation. Further research is required to establish reliability in ultrasound assessment as well as clear SLT driven protocols and training.

What this paper adds:

Ultrasound (US) has demonstrated potential as an assessment tool for objective parameters of swallowing. Use of US for laryngeal assessment (gross vocal fold movement) is also widely recognised within the literature. Our review appraised the

literature related to US as an alternative or adjunctive tool for assessment of swallowing and laryngeal function.

This paper identifies the current evidence base for US as a swallowing or laryngeal assessment tool is heterogenous and of variable quality. No study combined assessment of swallowing and laryngeal function, and only two studies assessed more than one parameter of swallowing, limiting the clinical application of the results.

Our review shows that US is a non-invasive accessible tool that can offer detailed focal assessment of swallowing and laryngeal function, such as hyoid displacement and vocal fold mobility. With development of protocols, training packages and competency standards, US has the potential to be used as an adjunct to SLT assessment of swallowing and laryngeal function. This is not currently enough evidence to support the use of US as a stand-alone tool for SLT assessment of swallowing or laryngeal function.

Introduction

Difficulties with swallowing (dysphagia) and laryngeal function comprise a large proportion of the caseloads of speech and language therapists (SLTs). Assessment of laryngeal function is an essential component of the swallowing assessment because of its role in airway protection and cough (Pitts, 2014). This is particularly true in populations where the underlying disease has multi-system effects, for example

patients with respiratory, neurological or neuromuscular conditions (Pitts et al., 2008, Bourke, 2014, McGrath et al., 2020).

The clinical management of dysphagia and laryngeal impairment relies on thorough information gathering. This includes detailed case history, direct examination, perceptual evaluation and diagnostic tests (Suiter and Gosa, 2019). SLTs use instrumental assessments to gain objective information about the functional anatomy of key structures and their related biomechanics. They are an essential part of the SLT toolkit to guide diagnostics, evidence-based decision-making, goal setting and rehabilitation. The most routinely used instrumental assessments include videofluoroscopic swallowing study (VFSS), flexible endoscopic evaluation of swallowing (FEES) and endoscopic evaluation of the larynx (EEL) (Martin-Harris and Jones, 2008, Wallace et al., 2020, Jones et al., 2020). Whilst these tools offer clear imaging of swallowing and laryngeal biomechanics, measurement of movement is cumbersome and requires image extraction to external software to improve reliability. The invasive nature of FEES and EEL limits accessibility and VFSS must be conducted in an upright posture in a radiology suite.

The COVID-19 pandemic has restricted access and provision of standard SLT procedures (VFSS, FEES, EEL) due to the risk of increased aerosol generation and disease transmission. (Tran et al., 2012, Bolton et al., 2020). SLTs are therefore exploring alternative lower risk tools to support the assessment of swallowing and laryngeal biomechanics.

Use of Ultrasound for Assessment of Swallowing and Laryngeal Function

An ultrasound (US) scan is a procedure that uses high frequency sound waves to capture images by placing a sound-emitting transducer directly onto the skin. This collects echoes reflected by the body part and transforms them into decoded signals to form an image (Aldrich, 2007). US has been used to study tongue, hyoid and laryngeal movement in swallowing (Shawker et al., 1984, Chi-Fishman, 2005, Nakamori et al., 2016), laryngeal function in post-surgical populations (da Costa et al., 2019) and guide extubation of patients in critical care (Ruan et al., 2018). It has not however been adopted into routine SLT clinical practice.

A Brazilian review (Leite et al., 2014) identified published studies using US to assess swallowing in adults and paediatrics between August 2002-2013. The review summarised 17 studies, of which 12 were based on an adult population. Hyoid bone movement was the most explored swallowing parameter, but methodological variability prevented any firm conclusions. Many studies used US as an outcome measure to assess differences between groups of different age or condition. Less than one quarter of included studies validated US against reference tools such as VFSS, FEES or EEL, limiting applicability to SLT. The authors reported that US was a fast, non-invasive, low-cost method for evaluating objective parameters of swallowing but made no recommendations for the use of US within SLT practice. Since this review there has been a considerable advancement in ultrasound technology and interest in its clinical application, warranting an updated review.

US assessment of laryngeal function has also been described fairly extensively within the literature (Noel et al., 2020) and reported to be a viable method to assess vocal fold function in a post-thyroidectomy population (Da Costa, 2019). Previous reviews made recommendations for further research into the use of US for assessment of swallowing and laryngeal function but without guidelines for implementation within clinical practice. The speed and portability, as well as overall safety and lack of radiation requirement, support the potential for wide application of US however limited evidence, and no obvious investment in training and skill acquisition, means US has not gained the same prominence as other tools such as VFSS and FEES.

The primary aim of this study was to explore the clinical utility of US as an assessment tool compared to gold standard routine SLT assessment tools in adults both with and without suspected swallowing or laryngeal dysfunction. Clinical utility was defined as the potential to contribute salient diagnostic information to determine oropharyngeal and laryngeal dysfunction. The secondary aim was to provide recommendations to inform the development of SLT-led US protocols and make suggestions for further research for its use in swallowing and laryngeal assessment.

Methods

This review was conducted by a group of eight acute hospital-based SLT clinical experts in response to the request for our national professional body (Royal College of Speech and Language Therapists; RCSLT) to provide a statement on the current

utility of US as a swallowing and laryngeal clinical assessment tool. Group membership comprised clinical academics who represented a range of patient populations and geographical regions.

A rapid review was conducted to locate primary research studies using US to assess swallowing and the laryngeal function. The review was based on the methodology and guidance for the conduct of rapid reviews developed by the National Collaborating Centre for Methods and Tools (Dobbins, 2017).

Search Strategy

Subject and methodological expertise, plus a scoping search of current literature, informed the search strategy. Published literature was identified via an electronic database search of: AMED <1985 to May 2020>, Ovid Emcare <1995 to 2020 week 21>, CINAHL and Medline Complete. Date limits were set for the period Jan 2010 - May 2020 with final searches for all databases completed on 28 May 2020. The following concepts were searched using free text in the title and abstract: ultraso*, sonograph*,ultrasonograph*, dysphag*, swallow*, deglut*, "pulmonary aspiration", "respiratory aspiration", "silent aspiration", "aspiration pneumonia", tongue, pharynx, larynx, laryngeal, "vocal cord*", "vocal fold*", "vocal ligament*", stridor, bolus, (oral OR pharyngeal) AND residue*. In addition, the concepts were mapped to thesaurus subject terms across databases: ultrasonography+, "deglutition disorders+", "pneumonia, aspiration", "respiratory aspiration", tongue+, pharynx+, larynx, "vocal cords".

Reference lists of included papers, other relevant reviews and background articles were scrutinised for additional citations. Experts with published work in the area were consulted and electronic alerts for key journals were set up to identify work published after 28th May 2020.

Inclusion and Exclusion Criteria

Review criteria were designed to reflect the broad scope but short timescales of the rapid review. A population, intervention, comparison, outcome (PICO) framework (Schardt et al., 2007) was used to identify primary studies of adults (population) who had undergone US assessment (intervention) alongside a reference test (VFSS, FEES, EEL or validated clinical assessment tool, clinician and/or patient-reported outcome measure) (comparison) where measurement of laryngeal function or swallowing (outcome) had been undertaken. For the purposes of the review, EEL was taken to include direct laryngoscopy (DL), flexible laryngoscopy (FL) or videolaryngoscopy (VL). Database filters were applied to include only English language and exclude papers with non-human participants and those using US to diagnose cancer. Studies that used novel or non-routine comparison tests, such as computerised tomography, manometry and muscle biopsy, were excluded as were papers that used US to assess head and neck structure, speech, mastication, intubation and extubation. Any papers with potential clinical utility within SLT but outside the scope of this review were collated as reference material.

Selection of publications for review

Database citations were downloaded to Rayyan Qatar Computing Research Institute (QCRI) systematic review web application (Ouzzani et al., 2016). Citations were divided into four equal pools and each pool allocated to one of four reviewers [JA, CS, CG, JH]. Each reviewer screened their pool at title and abstract level and allocated to one of three pre-determined options: 'include,' 'exclude' or 'maybe' based on meeting the PICO criteria. Criteria were refined through iterative discussion to allow resolution of all papers classified as "maybe" A fifth reviewer [SW] randomly sampled 10% of each pool for accuracy and any disagreements settled by an additional reviewer [RG].

Five reviewers [JA, CS, JH, CH, GC] used a bespoke data extraction form on two full-text papers as part of a pilot process to discuss and agree standards for data extraction. Data extracted included: primary author and year of publication; country of origin and setting; study design; population and sample size; index and reference test detail; protocol and reliability information as well as key outcomes and findings. Where data formed a section of a multi-part study, only data from the included sub-study were extracted. Full texts were divided between the five reviewers and assessed; papers were excluded from further analysis if they did not meet inclusion criteria.

Critical Appraisal

Final full-text papers were assessed for quality using the QUADAS-2 tool (Whiting et al., 2011) which assesses four key domains including patient selection, index test, reference standard, and flow of patients through the study and timing of the index

test(s) and reference standard. Each study was scored (high, low or unclear) across the four domains. Applicability to a population was scored based on the first three domains only. An a priori decision was made to judge applicability of US as the index test unclear for all papers. This was due to the lack of consensus in the literature around standard test conduct and interpretation for swallowing and laryngeal function. The tool was piloted on one paper by all five reviewers and criteria refined through discussion and consensus. Swallowing papers were assessed by JA, CMG and GC and laryngeal function papers by CS, JH, GC and JA.

Analysis and Synthesis of Data

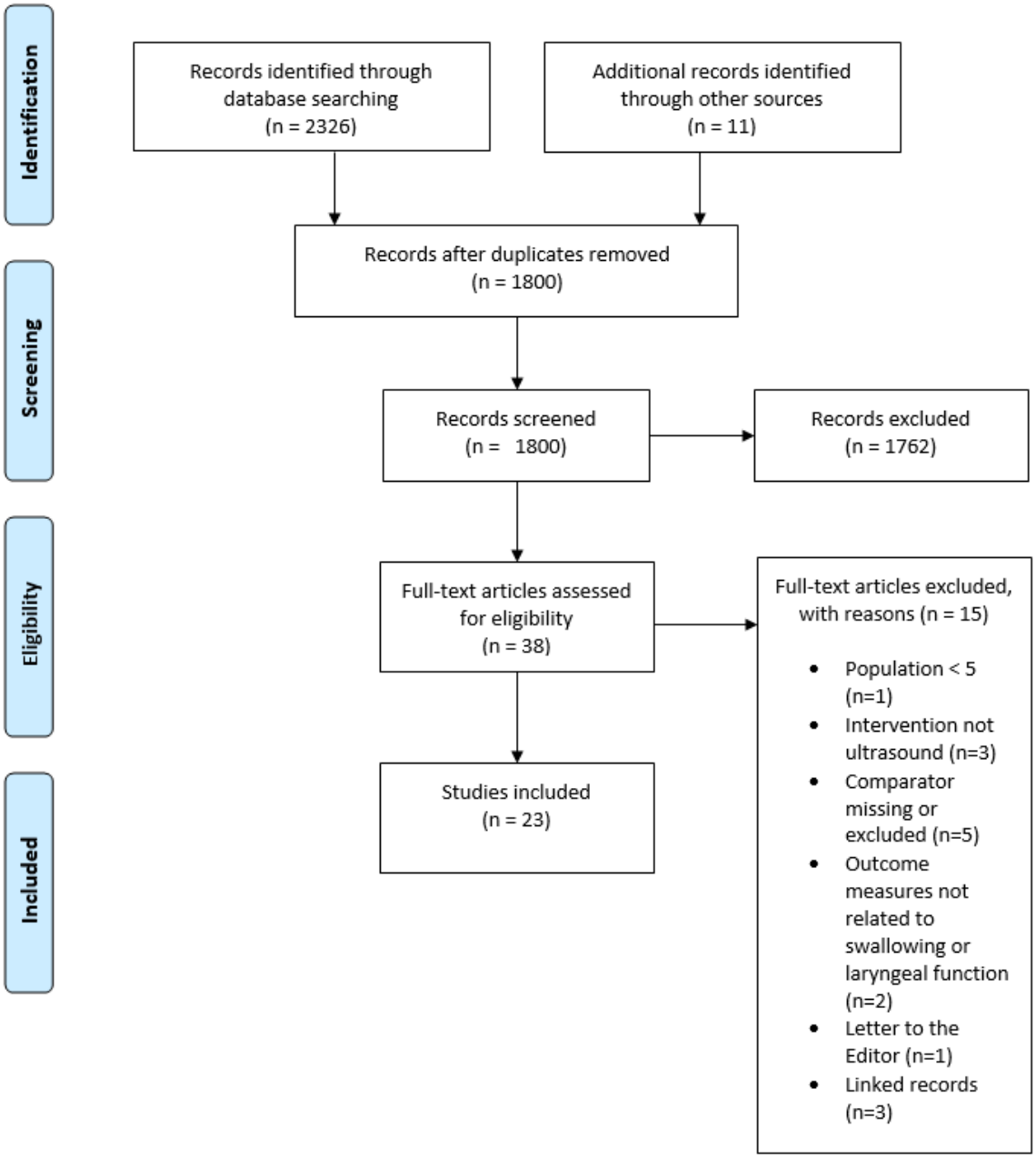
Information from included studies was summarised using tools and techniques of narrative synthesis (Popay et al., 2006). This included textual description, grouping and clustering. Visual illustration of findings to show sensitivity, specificity and associated confidence intervals was used where indicated. For studies in which values were missing but sufficient raw data was reported, confidence intervals were calculated using an online calculator http://vassarstats.net/. These studies are identifiable in the summary of included studies (Table 1).

Quality assessment findings from QUADAS-2 were summarised into a table by one reviewer with expertise in both swallowing and laryngeal function (GC). Three reviewers agreed a pre-defined quality scoring system (GC, JH, CS) with final agreement by the first author (JA). High, low or unclear scores for risk of bias and applicability concerns were given to each study based on this system.

Results

Database searching resulted in a total of 2326 papers, with 11 additional records identified through other sources. Deletion of duplicates, abstract and full-text screening resulted in 23 primary studies for inclusion in the final review. The Preferred Reporting Items for Systematic Reviews and Meta-Analyses (Moher et al., 2009) flow diagram summarises the search results and reasons for full-text exclusion in Figure 1.

Figure 1: PRISMA flow diagram


Identification
Screening
Eligibility
Included
Records identified through database searching (n = 2326)
Additional records identified through other sources (n = 11)
Records after duplicates removed (n = 1800)
Records screened (n = 1800)
Records excluded (n = 1762)
Full-text articles assessed for eligibility (n = 38)
Full-text articles excluded, with reasons (n = 15)
Population < 5 (n=1)
Intervention not ultrasound (n=3)
Comparator missing or excluded (n=5)
Outcome measures not related to swallowing or laryngeal function (n=2)
Letter to the Editor (n=1)
Linked records (n=3)
Studies included (n = 23)

Types of studies, setting and context

An overview of study design, setting and context is provided in table 1. Ten out of the 23 studies were associated with swallowing, and thirteen with laryngeal function. The first four sections of table 1 summarise the swallowing studies, listed in order of the oral phase (tongue movement, n=1), pharyngeal phase (hyolaryngeal movement, n=4 and posterior pharyngeal wall movement, n=2) and swallowing symptoms (residue n=2, penetration/aspiration n=1). The final two sections summarise the laryngeal studies which include vocal fold (n=12) and vocal fold plus oedema (n=1) studies.

Swallowing studies originated from East Asia [Japan (n=4); Korea (n=2); Taiwan (n=1); Hong Kong (n=1)] and Italy (n=2) whilst laryngeal studies were more geographically diverse [Hong Kong (n=3); South Korea (n=1); India (n=3); USA (n=3); Italy (n=1); Spain (n=1);Egypt (n=1)]. Studies were prospective observational (n=19), cross-sectional (n=3) and case-series (n=1). All except one of the swallowing studies were undertaken in a hospital setting, the remaining being a motor neuron disease referral centre (Tamburrini et al., 2010). The laryngeal studies were all conducted in a hospital setting except one where the setting was unclear (Kumar et al., 2018).

Table 1: Characteristics of included studies

Legend*: PO* Prospective observational, *X-S* cross-sectional, *CS* case series, *vs.* versus, *SD* standard deviation, *IQR* Inter-quartile range, *PPF* Positive predictive value, *NPF* Negative predictive value, *CI* confidence interval, *MND* Motor Neurone Disease, *US* ultrasound, *VFSS* Videofluoroscopy swallowing study, *FEES* Fibreoptic endoscopic evaluation of swallowing, *DL* Direct laryngoscopy, *PAS* Penetration aspiration scale (ref), *VF* vocal fold, *sig.* significant *dif.* difference * Sub-group of a larger population which also included n=22 normal controls for a two-part reliability study, ** Sub-group of a larger population which also included n=4 normal controls for a two-part study where part 1, Underline indicates confidence intervals which have been calculated by review authors for purpose of synthesis.

Author (ref.), year **Country, setting**	**Study design**	**Sample size (n)**	**Population description** Age presented as: mean (range) or mean (SD) unless specified	**Index test equipment**	**Reference test**	**Protocol described (YES/NO)**	**Reliability reported (YES/NO)**	**Outcomes**	**Findings**
Oral Phase Swallowing Studies									
Tamburrini *et al.* 2010. Italy, MND referral centre	PO	n= 9	MND Mean (range) disease duration 15 (6-33) months. 44% female; age 60 (33-76) years.	ProFocus US system (B-K Medical). 5-MHz microconvex probe (type 8803) & direct video-capturing software of 25 frames/s with option to slow and freeze.	VFSS to define: - bolus position in mouth - inability to retain bolus in oral cavity - reduced & disorganised tongue movement - fragmented swallowing - pooling of ingested material	YES Index & Reference	NO	Six parameters: - tongue atrophy - abnormal bolus position - inability to retain bolus in oral cavity - reduced & disorganised tongue movement - fragmented swallowing	US > VFSS for identification of: - abnormal bolus position (6/9 vs. 3/9) - reduced tongue movement (5/9 vs. 2/9) - disorganised tongue movement (3/9 vs. 2/9) - fragmented swallowing (6/9 vs. 0/9). US = VFSS for identification of inability to retain bolus in mouth (4/9).

								- pooling of ingested material Diagnostic markers described for each measure.	US < VFSS for identification of pooling (2/9 vs 0/9).
Pharyngeal phase swallowing studies (hyo-laryngeal movement)									
Chen *et al*, 2017. Taiwan, hospital.	PO	n=10	Mixed patient cohort. 0% female; age = 71.8 (54-81) years.	Self-designed US. 3.5 MHz curvilinear transducer recorded at 30 frames/second	VFSS to measure maximum hyoid displacement before and during swallowing.	YES Index & Reference	YES Interrater intraclass correlation coefficient (ICC) between two examiners 0.892 ($p<0.05$). ICC between US and VFSS 0.815 and 0.915 for each researcher ($p<0.01$).	Hyoid bone displacement: distance between hyoid bone and mandible at rest and during swallowing.	No sig. dif. between results of US and VFSS ($p = 0.437$). ICC between VFSS and US for two researchers = 0.815 and 0.916 ($p<0.001$).

Cheng *et al.*, 2018. Hong Kong, hospital.	PO X-S	n=40	Post radiotherapy nasopharyngeal carcinoma patients. ≥3 years post treatment. 23% female; mean age = 53.9 years.	B-mode submental US portable system (Mindray). 6-14MHz linear transducer.	VFSS to define: - Anterior hyoid displacement - Superior hyoid displacement	YES Index & Reference	YES Intrarater agreement for US and VFSS; and interrater agreement for US and VFSS. All values ICC ≥0.75 (p <.001)	Geniohyoid contraction: % increase of coronal cross-sectional area.	% increase in cross-sectional area of geniohyoid correlated with anterior hyoid displacement. Pearson correlation coefficient 0.42 (p=0.008) No correlation with superior hyoid displacement (r=0.27, p=0.09)
Lee *et al.*, 2016. Korea, hospital.	PO	n= 52	Patients with dysphagia (n=23 ischaemic stroke; n-= 22 haemorrhagic stroke; n=7 other). 35% female; age = 61.2 (16.4) years.	LOGIQ E9 US (GE Healthcare). 1-5MHz curved probe.	VFSS to define: - Penetration (PAS 1-8) - Residue (Grades 0-3) Sub-groups: - Non-aspirators - Penetrators - Aspirators Plus: - No residue - <10% residue - >10% <50% residue - ≥50%	YES Index only	NO	Hyoid bone displacement: distance between hyoid bone and mandible at rest and during swallowing. % displacement = hyoid displacement, mm, /resting distance, mm, x 100.	Displacement distance sig. (p<0.001) shorter in penetrators & aspirators group than non-aspirators group. % displacement sig. smaller in penetrators (p=0.001) and aspirators (p<0.001) than non-aspirators. % displacement in aspirators sig. smaller than penetrators (p=0.002). Cuff-off value of 13.5mm for hyoid displacement (sensitivity 83.9%, specificity 81.0%) & 30.3% hyoid bone % displacement (sensitivity

					residue				64.5%, specificity 95.2%) to define non-aspirators vs penetrators/aspirators. Mean hyoid bone displacement & % hyoid displacement both sig. smaller for group with >10% post-swallow residues in piriform fossae than no residue (p=0.001) and <10% residue in the piriform fossae (p=0.004). Sig. dif. in mean hyoid displacement between: No residue & <10% group (p=0.036). Sig. dif. in mean hyoid displacement and % hyoid displacement between: No residue & >10% group (p<0.001). <10% residue & >10% residue group (p=0.005).
Picelli *et al.,* 2020. Italy, hospital.	PO	n=19	Acute stroke (n=14 ischaemic; n-= 5 haemorrhagic). Mean (SD) disease	DC-40 US system (Mindray). 6 MHz linear probe.	Gugging Swallow Screen (GUSS): - Score 0 (worst performance) to 20 (best performance).	NO	NO	% degree of hyoid-larynx approximation. % displacement = resting distance between hyoid and thyroid -	Sig. direct association between FOIS and hyoid-larynx approximation distance (p=0.011 and r=0.571) and degree (%) (p=0.005 and r=0.614). Sig. direct association between GUSS and hyoid-

			duration 2.7 (2.1) days. 47% female; age = 71.9 (15.5) years.		Functional Oral Intake Scale (FOIS): - Scores 1-6 denotes dysphagia - Score 7 denotes no dysphagia			shortest distance between the hyoid and thyroid during swallowing/ initial resting distance, x 100.	larynx approximation distance (p=0.008 and r=0.590) and degree (%) (p=0.004 and r=0.628). Sig. dif. between dysphagic and not dysphagic WRT hyoid-larynx approximation distance (p=0.013 and z=-2.494) and degree (p=0.011 and z=-2.531).
Pharyngeal Phase Swallowing Studies (posterior pharyngeal wall movement)									
Kim *et al.*, 2012. Korea, hospital.	PO	n=26	Stroke (n=18 ischaemic; n-= 8 haemorrhagic). Mean (SD) disease duration 3.6 (5.2) months. 65% female; age = 60 (13.6) years.	ACUSON Antares US system, premium edition (Siemens Medical Solutions). 5.71MHz electronic convex array transducer (Model CH 6-2), B-mode and M-mode.	VFSS to define aspiration/ penetration (group A) vs. not (group B). VFSS parameters compared with US: - pharyngeal transit & delay time (PDT) - triggering of pharyngeal swallow - valleculae & pyriform residue	YES Index & Reference	NO	Lateral pharyngeal wall (LPW) displacement and duration, of weak side.	LPW displacement smaller in group A (0.51±0.37) than group B (0.94 ±0.43) but not significant (p=0.633). <u>Group A</u> LPW displacement significantly correlated with: -Laryngeal elevation (r=0.71, p=0.047) -PDT (r= -0.78, p = 0.021) -Valleculae residue (r=-0.94, p=0.0001) No correlation with PTT, triggering of pharyngeal swallow or piriform residue (p>0.05).

									<u>Group B</u> LPW displacement & duration not sig. correlated with residue in the piriform or valleculae, PTT, triggering of pharyngeal swallow, PDT or laryngeal elevation (p>0.05).
Manabe *et al.,* 2012. Japan, hospital setting.	PO	n=56*	Patients with mild oropharyngeal dysphagia (n=56). 54% female; age = 58.0 (13.7) years.	Aplio XG US system (Toshiba Medical Sysyems). 12MHz linear array transducer.	VFSS to define: - Timing of opening and closing of the upper oesophageal sphincter (UES)	YES Index & Reference	YES	Parameters: - maximal movement distance of posterior pharyngeal wall (CE) wall (mm) - CE wall opening time (ms) - Duration and velocity of CE wall opening & closing	Sig. positive correlation between duration of CE wall opening on US and duration of UES opening on VFSS (r=0.86, p<0.001).
Studies of Swallowing Symptoms (Residue and Aspiration)									
Miura *et al.*, 2014. Japan, hospital. Outpatient	X-S	n=17	Mixed patient cohort. <u>Group 1 (n=8):</u> Aspirators. 0% female;	Portable US M-Turbo (Sonosite). 5-15MHz linear array transducer.	VFSS & FEES Binary assessment of aspiration (presence vs absence)	YES Index & Reference	NO	Aspiration: Passage of a hyperechoic object through the VF with movement different from	Of 42 images US correctly detected: -Aspiration in 7/11 images identified via VFSS/FEES. -Absence of aspiration in

clinic.			age = 71 (9.2) years. <u>Group 2 (n=9):</u> Non-aspirators. 11% female; age = 69 (6.2) years.					the surrounding structure.	26/31 also not identified via VFSS/FEES. Aspiration detection on US = 64% sensitivity; 84% specificity (kappa coefficient 0.66).
Miura *et al.*, 2016. Japan, hospital. Outpatient clinic.	X-S	n=9	Mixed patient cohort (n=5 stroke; n= 1 Parkinson's disease; n= 1 Pneumonia; n=1 Amyotrophic lateral sclerosis; n=1 healthy). 11% female; mean age = 70 years.	Portable US M-Turbo (Sonosite). 5-15MHz linear array transducer.	FEES Binary assessment of residue (presence vs absence)	YES Index & Reference	NO	Post-swallow pharyngeal residue: proportion of high-echogenicity area to the pyriform sinus and vallecula.	19 images from 9 participants. Detection of pharyngeal post-swallow residue on US = 62% sensitivity; 67% specificity.
Miura *et al.*, 2020. Japan, hospital.	X-S	n=35**	Mixed patient cohort with dysphagia (n=35). 26% female; age = 80.4 (10.6) years.	Handheld US Sonosite iViz (Fujifilm). 5-10 MHz or 6-13 MHz linear array transducers.	FEES Classification for level of residue in pyriform fossae (PF) and valleculae (V): -none (no boluses or	YES Index & Reference	NO	Post-swallow pharyngeal residue: proportion of high-echogenicity area to the pyriform sinus and vallecula. US to detect	Cut off <0: PF = 92.0% sensitivity (CI 86.9-95.5); 71.9% specificity (CI 59.2-82.4) V = 86.7% sensitivity (CI 75.4-94.1); 63.6% specificity (CI 40.7-82.8). Cut off ≤0.05* PF = 87.9% sensitivity (CI

					secretions) -mild (>50% PF or V covered -severe (<50% PF or V covered)			residue based on echogenicity at cuff-off points <0, ≤0.05, ≤0.1 and ≤0.5 representing % of high echogenicity area.	82.1-92.4); 78.1% specificity (CI 66.0-87.5) V = 85% sensitivity (CI 73.4-92.9); 81.8% specificity (CI 59.7-94.8). Cut off ≤0.1 PF = 79.3% sensitivity (CI 72.5-85.1); 84.4% specificity (CI 73.1-92.2) V = 75% sensitivity (CI 62.1-85.3); 86.4% specificity (CI 65.1-97.1). Cut off ≤0.5 PF = 21.3% sensitivity (CI 15.4-28.1); 98.4% specificity (CI 91.6-100) V = 5% sensitivity (CI 1.0-13.9); 100% specificity (CI 84.6-100).
Laryngeal Studies (vocal fold movement)									
Amis *et al.*, 2012. USA, hospital.	PO	n=16	Patients with known vocal fold motion abnormalities or perioperative patients having surgery presenting risk to the recurrent	US; no details of machine provided. High frequency (unstated range) linear probe.	DL Binary assessment (normal vs impaired)	YES Index only	NO	Correlation of US and DL findings for VF motion. Data assessed from US image: 1.Alignment of non-phonating VF in relation to the midpoint	Congruent findings on 13/16. US to detect VF motion abnormality: - 71% sensitivity (CI 30.2-94.8) - 89% specificity (CI 50.7-99.4) - PPF = 83%

			laryngeal nerve. ?% female; age range = 18-80 years.					between them to assess any supero-inferior pre-existing misalignment 2. Latero-medial and/or supero-inferior movements of the VFs during phonation in relation to the midpoint between them. If noted a supero-medial pull on VFs = 'tenting'(abnormal)	- NPV = 80%
Caneiro-Pla *et al.*, 2014. USA, hospital.	PO	n= 510	Pre-operative patients due to undergo cervical surgery. 85% female; age range = 18-86 years.	Multiple US systems & probes.	Indirect laryngoscopy. Binary assessment (normal vs impaired). Only n=70 had reference test.	YES Index only	NO	Visualisation of bilateral VF movement.	377/510 visualisation of bilateral VF movement. In n=70: Sensitivity 100% Specificity 98% Accuracy 99% Visualisation greater in females vs. males (83% vs. 17%, p=0.0005). Thyroid cartilage calcification affected visualisation vs. no thyroid

									cartilage calcification (42% vs. 81%, p=0.0005).
Dubey *et al.*, 2018. India, hospital.	PO	n= 100	Patients listed for thyroidectomy. 67% female; median (IQR) age = 45 (33-54) years.	Micromaxx US system (Sonosite). 6-13 MHz linear array transducer.	DL & video laryngoscopy. Binary assessment (normal vs immobile).	YES Index & Reference	YES Perfect agreement for subjective VC assessment (κ=1.00, 95% CI =1.00-1.00); near perfect for VFDV (κ=0.9994, 95% CI = 0.9993-0.9995).	Mobility assessment of VFs and VF displacement velocity (VFDV) assessment using US compared with laryngoscopy assessment. Distinction between mobile, impaired, immobile VCs and normal VCs.	Correlation of US and DL (r=0.93, p<0.0001). Correlation of US and video laryngoscopy (r=0.83, p<0.0001). Pre-op: r=-0.32 95% CI 0.44 to -0.19 p<0.0001 Post-op: r=-0.29, 95% CI -0.40 to -0.15 p= <0.0001
Fung *et al.*, 2020. Hong Kong, hospital.	PO	n= 65	Patients undergoing elective neck surgery that may pose risk to 1 or both recurrent laryngeal nerves.	Portable US system (General Electric). 4-13 MHz linear probe.	DL Grading system: - Normal - Grade 1 (decreased movement) - Grade 2 (absence of	YES Index only	NO	US immediately after endotracheal extubation in the recovery room to define: grade I =	n=61 successful US; 94% feasibility. 100% correlation between DL & US; grading of movements 100% correlation. Sensitivity 100% (CI 100%

			68% female; median (range) age = 57 (46-69) years.		movement)			normal movement grade II = decreased movement grade III = complete absence of movement	(46.3-100) Specificity 100% (CI 92-100) PPV 100% NPV 100% Accuracy 100%
Gambardella *et al.*, 2020. Italy, hospital.	PO	n= 396	Patients diagnosed with benign and malignant thyroid disease (pre-operative). 66% female; age = 56.4 (18-82) years.	MyLab™ X5 (Esatoe). 7–13-MHz linear probe.	DL Binary assessment (normal vs impaired). based on three manoeuvres.	YES Index & Reference	NO	US to classify normal vs impaired VF function based on same parameters of DL assessment. Notes made on: -movement -weakness -asymmetry -paralysis	Accessibility rate of US = 96%. US to detect VF alteration: - 96.8% sensitivity (CI 94.4-98.2) - 95.6% specificity (CI 93-97.3) PPV 65.2% (CI 60.3-79.9) NPV 99.7% (CI 98.3-100)
Kandil *et al.*, 2016. USA, hospital.	PO	n= 250	Pre & post-operative parathyroid & thyroid surgery patients. 83.2% female; age = 52.7 (14.3) years.	US; no details of machine provided. 12-MHz linear transducer.	DL Binary assessment (normal vs impaired).	YES Index only	NO	US assessment of active VF movement – classified as normal or impaired.	US to detect VF function pre-op: - 53.8% sensitivity CI (0.26-0.79) - 50.5% specificity (CI 0.46-0.55) - 50.6% accuracy - PPV 2.8% - NPV 97.6% US to detect VF function

									post-op: - 55.6% sensitivity (CI 0.35-0.74%) - 38.7% specificity (CI 0.34-0.43%) - 39.6% accuracy - PPV 4.9% - NPV 91.1%
Kumar *et al.*, 2018. India, setting unclear.	PO	n= 65	Patients undergoing thyroid surgery pre- and post-operative (benign or malignant). 72% female; median (range) age = 44 (23-60) years.	Portable US (Sonosite). High frequency (8-12 MHz) linear probe.	DL Binary assessment (normal vs impaired).	YES Index only	NO	Normal vs abnormal movement on US. Normal movement defined as symmetrical abductive and adductive motion of true VC during quiet respiration.	US to detect VF paralysis: - 100% sensitivity (CI= 0.34,1.00) - 93.44% specificity (CI = 0.84, 0.97)
Miguel *et al.*, 2017. Spain, hospital.	PO	n= 93	Patients undergoing total thyroidectomy (pre-and post-operative). 78% female; >18 years old (no further age statistics	Portable US (Mylab 25 Gold). 5-10 MHz linear probe.	DL Binary assessment (normal vs VF palsy). Normal mvmt = symmetrical abduction and adduction of true	YES Index only	NO	Evaluation of the accuracy of immediate postoperative period US to diagnose VF paralysis. *True positive* = decreased/absent VF	Accessibility rate of US pre-op = 94% (p=0.99). US to detect VF palsy: -66.67% sensitivity (CI 7.4-100%) -100% specificity (CI99.4-100%) -PPV 100% (CI 75-100%) -NPV 98.9% (96.2-100%)

			reported).		VFs at rest and in phonation. VF palsy = decreased/absent movement.			movement on US & confirmed palsy on DL *True negative* = normal VF movement on US & confirmed palsy on DL *False positive =* indications of abnormal VF movement on US & normal cord mobility on DL *False negative* = no abnormal VF movement on US & decreased/absence mobility on DL	Accessibility rate of US post-op = 93% (p=0.99). US to detect VF palsy: - 93.3% sensitivity (95% CI:77.3-100%) - 96.1% specificity (95% CI:91.2-100%) - 82.3% PPV (95% CI:61.2-100%) - 98.6% NPV (95% CI:95.4-100%)
Shah *et al.*, 2019. India, hospital.	PO	n=45	Patients pre- and post-thyroidectomy (benign or malignant). 87% female; age = 42.02	Portable US system (Sonosite). High frequency (5-10 MHz) linear probe.	DL Binary assessment: -bilateral mobility -unilateral mobility	YES Index only	NO	US mobility assessment of VFs as per DL.	US to detect VF palsy: - 75% sensitivity (CI 21-99%) - 95.1% specificity (CI 85.2-99.8%) - PPF = 60% - NPV = 97.5%

			(15.1) years.		-could not be assessed				
Woo *et al.*, 2017. South Korea, hospital.	PO	n=301	Patient with post-operative thyroidectomy and other neck operations. 82% female; median (range) age = 48 (13-81) years.	High definition US system (Philips). High (12 - 5MHz) and low (9-3MHz) frequency.	DL Grading system: 1 = normal, symmetrical movement 2 = impaired or decreased movement 3 = no movement	YES Index & Reference	NO	High and low frequency US to score VF mobility using same grading system as DL.	High frequency US to assess VF motion: - 88.4% visualisation - 92.9% sensitivity (97.5% sensitivity CI85.3-99.8) - 86.5% specificity (99.1% sensitivity CI 96.5-99.8) Low frequency US to assess VF motion: - 97.7% visualisation - 97.6.9% sensitivity (97.6% sensitivity CI 85.9-99.8) - 96.5% specificity (99.2% specificity CI 96.8-99.8)
Wong *et al.*, 2014. Hong Kong, hospital.	CS	n= 118	Patients undergoing thyroidectomy. Group 1 (n=51): vocal cord asymmetry. 92% female; median	Portable US system iLookTM 25 (Sonosite). 5–10 MHz linear transducer.	GRBAS scale and voice impairment scale.	YES Index only	NO	Post-operative VF asymmetry detected by US correlates with voice alteration.	Group 1 significantly worse GRBAS 'G' score (0.24 vs., 0.07, p=0.016), 'R' score (0.33 vs. 0.14, p=0.022) pre & post-operation, compared to Group 2.

			(range) age = 50 (13-83) years. <u>Group 2 (n=118):</u> no vocal cord asymmetry 83.8% female; median (range) age = 51 (19-78) years.						
Wong *et al.*, 2019. Hong Kong, hospital Linked records: (Wong et al., 2013) (n=204) (Wong et al., 2015) (n=581) (Wong et al., 2017) (n=1000) NB The latest &	PO	n=1196	Patients undergoing thyroidectomy (or other neck procedure), pre- and post-operative assessment. 79% female; median (range) age = 51 (20-84) years.	Portable US system iLookTM 25 (Sonosite). 5–10 MHz linear transducer.	DL Grading system: 1 = full or normal, movement 2 = impaired or reduced movement in ≥1 VC 3 = no movement in ≥1 VF	YES Index only	NO	US to grade VF movement as per DL. Patients dichotimised into normal (grade 1 vs abnormal grade 2 or 3).	Diagnosis grade of VF movement on US: - 85.3% sensitivity <u>(CI 0.74-0.92)</u> - 94.7% specificity <u>(CI 0.92-0.95)</u> PPV 47.9% NPV 99.0%

largest cohort has been used for analysis									
Laryngeal Studies (vocal fold movement & oedema)									
Kamel *et al.*, 2020. Egypt, hospital.	PO	n= 90	Patients scheduled for anterior cervical spine surgery. 36.7% female; 31.1% <50 years.	M Turbo US system (Sonosite). 7–10 MHz linear transducer.	Rigid laryngoscopy Binary assessment (normal vs vocal cord paralysis).	YES Index only	NO	Pre & post-operative VF oedema: - Laryngeal air-column difference - VF thickness (mm) Pre & post-operative VF paralysis: -VF movement in breathing and phonation	Diagnosis of post-operative VF oedema on anterior US: - 88.2% sensitivity (CI 62-98%) - 95.1% specificity (CI 54-93%) - PPV = 78.9% - NPV = 88.2% Diagnosis of post-operative VF oedema on lateral US: - 88.2% sensitivity (CI 62-98%) - 94.7% specificity (CI 71-99.7%) - PPV = 93.7% - NPV = 90% Diagnosis of post-operative VF paralysis on anterior US: - 86.7% sensitivity (CI 74-92%) - 85.7% specificity (CI 92-95%)

									- PPV = 81.25% - NPV = 90% Diagnosis of post-operative VF paralysis on lateral US: - 100% sensitivity (CI 74.6-100) - 100% specificity (CI 80.7-100) - PPV = 100% - NPV = 100%

Study Populations

Patient population across the ten swallowing studies included stroke (n=2) (Kim et al., 2012, Picelli et al., 2020), motor neuron disease (n=1) (Tamburrini et al., 2010), post-radiotherapy (n=1) (Cheng et al., 2018) and mixed inpatient cohorts (n=6) (Chen et al., 2017, Manabe et al., 2018, Lee et al., 2016, Miura et al., 2014, Miura et al., 2016, Miura et al., 2020). In the 13 laryngeal studies, nine included populations undergoing thyroid surgery (n=7) (Dubey et al., 2019, Shah et al., 2019, Kumar et al., 2018, de Miguel et al., 2017, Kandil et al., 2016, Gambardella et al., 2020, Wong et al., 2014), thyroid surgery plus other endocrine-related neck procedures (n=1)(Wong et al., 2019) or other neck operations (n=1) (Woo et al., 2017). The four remaining studies included participants undergoing neck surgery presenting risk to the recurrent laryngeal nerve (n=2) (Carneiro-Pla et al., 2014, Fung and Lang, 2020), a mixed neck and vocal fold population (n=1) (Amis et al., 2012) and patients undergoing anterior-cervical (AC) spinal surgery (n=1) (Kamel et al., 2020).

The 10 swallowing studies had a combined total of 273 participants, with a mean number of 27 and range of 9 (Tamburrini et al., 2010, Miura et al., 2016) to 56 (Manabe et al., 2018). The laryngeal function studies had a total of 3,245 participants, with a range of 16 (Amis et al., 2012) to 1196 (Wong et al., 2019).

Participant gender was reported in all ten swallowing studies and eleven of the laryngeal studies with 133 female (35.6%) and 240 (64.4%) male, and 2396 female (77%) and 715 males (23%) participants in each respective subgroup.

Participant age was reported in all studies of swallowing and nine (9/13) studies of laryngeal function with a range of 33 to 91 years and 13 to 86 years respectively. Mean age of participants across swallowing studies was 65.7 years (SD = 7.82), ranging from 53.9 to 80.4. Mean age of participants across laryngeal studies was 50.5 years (SD = 5.98), ranging from 42 to 58. Papers with a threshold age of <18 years were included as the median age reflected a majority adult cohort.

Ultrasound Index Test

A range of US equipment was used, including console devices n=9 (Tamburrini et al., 2010, Lee et al., 2016, Picelli et al., 2020, Kim et al., 2012, Manabe et al., 2018, Dubey et al., 2019, Gambardella et al., 2020, Woo et al., 2017, Kamel et al., 2020) portable (n=9) (Cheng et al., 2018, Miura et al., 2014, Miura et al., 2016, Fung and Lang, 2020, Kumar et al., 2018, de Miguel et al., 2017, Shah et al., 2019, Wong et al., 2014, Wong et al., 2019) handheld (n=1) (Miura et al., 2020), self-made (n=1) (Chen et al., 2017) or combination of multiple systems (n-=1)(Carneiro-Pla et al., 2014). In all but one swallowing study (Picelli et al., 2020) a protocol for conducting the US assessment was reported. Probe and frequency selection varied across the included studies and only four studies provided inter and intra-rater reliability data (Chen et al., 2017, Cheng et al., 2018, Manabe et al., 2018, Dubey et al., 2019).

Reference Tests

Six studies (60%) used VFSS to compare US assessment of swallowing biomechanics and/or bolus flow (Tamburrini et al., 2010, Goetz et al., 2019, Cheng et al., 2018, Lee et al., 2016, Kim et al., 2012, Manabe et al., 2018). One study (Picelli *et al.* 2020) used

the Gugging Swallow Screen and Functional Oral Intake Scale as a comparator. Two (Miura et al., 2016, Miura et al., 2020) used FEES to compare with US identification of residue, whilst the third used a combination of FEES and VFSS (Miura et al., 2014) to identify aspiration. A protocol for the reference test is described for all but two of the swallowing papers (Lee et al., 2016, Picelli et al., 2020). All studies of laryngeal function compared US findings with EEL except one which used a voice impairment scale and GRBAS voice quality perceptual rating (Wong et al., 2014). A reference-test protocol was described in only three studies (Dubey et al., 2019, Gambardella et al., 2020, Woo et al., 2017). No studies provided data on rater reliability.

Quality Assessment

A summary of the quality assessment findings can be found in Table 2 below. Each score (high, low or unclear) is represented symbolically.

Table 2: Quality Assessment of Studies using QUADAS-2

	RISK OF BIAS				APPLICABILITY CONCERNS		
	PATIENT SELECTION	INDEX TEST	REFERENCE STANDARD	FLOW AND TIMING	PATIENT SELECTION	INDEX TEST	REFERENCE STANDARD
Oral phase swallowing studies							
Tamburrini *et al.* 2010	☹	☹	☹	☺	☺	?	☺
Pharyngeal phase (hyolaryngeal movement) swallowing studies							
Chen *et al.* 2016	☹	☹	☹	☺	☺	?	☺
Cheng *et al.* 2018	☹	☹	☹	?	☺	?	☺
Lee *et al.* 2016	☹	☹	☹	☺	☺	?	☺
Picelli *et al.* 2020	?	☹	☹	?	☺	?	☺
Pharyngeal phase (pharyngeal wall movement) swallowing studies							
Kim *et al.* 2012	☹	☹	☹	?	☺	?	☺
Manabe *et al.* 2012	☺	☺	☺	☺	☺	?	☺
Studies of swallowing symptoms							
Miura *et al.* 2014	?	☺	☺	☺	☺	?	☺
Miura *et al.* 2016	☹	?	☺	☺	☺	?	☺
Miura *et al.* 2020	?	☺	☺	☺	☺	?	☺
Laryngeal function (vocal fold movement) studies							
Amis *et al.* 2012	?	☺	☺	?	?	?	☺
Caneiro-Pla *et al.* 2014	☹	☺	☹	☹	☹	?	☺
Dubey *et al.* 2018	☹	☺	☺	☺	☹	?	☺
Fung *et al.* 2020	☺	☺	☺	☺	☹	?	☺
Gambardella *et al.* 2020	?	☺	☺	?	☹	?	☺
Kandil *et al.* 2016	☹	☺	☹	☺	?	?	☺
Kumar *et al.* 2018	?	☺	☺	☺	☹	?	☺
Miguel *et al.* 2017	☺	☺	☺	☺	☹	?	☺
Shah *et al.* 2019	☹	☺	☺	☺	☹	?	☺
Woo *et al.* 2017	☺	☺	☺	☺	☹	?	☺
Wong *et al.* 2014	☹	☺	☹	☺	☹	?	☹
Wong *et al.* 2019	☹	☺	☺	☺	☹	?	☺
Laryngeal function (vocal fold movement and oedema) studies							
Kamel *et al.* 2020	☹	☺	☺	☹	☺	?	☺

Risk of Bias

One swallowing paper (Manabe et al., 2018) and three laryngeal papers (de Miguel et al., 2017, Woo et al., 2017, Fung and Lang, 2020) had low risk of bias across all four domains. These studies employed consecutive patient selection, appropriate exclusion criteria, blinding and appropriate interval between the index and reference test. Several studies did not recruit consecutive patients and/or patients

with potential swallowing or laryngeal difficulties were excluded. Two of the laryngeal studies (Carneiro-Pla et al., 2014, Kandil et al., 2016) exhibited high risk of bias due to unblinded assessors. Nine out of ten swallowing studies either did not report or did not employ blinding between reference and index test.

Applicability

All ten swallowing studies and one laryngeal study (Kamel et al., 2020) scored as low for concerns regarding applicability of patient selection. Ten of the laryngeal studies scored high for applicability concerns relating to patient selection. These papers included either a paediatric age range (<18 years) (Wong et al., 2014, Woo et al., 2017, Dubey et al., 2019) or presence of endocrine malignancy in the patient cohort (Woo et al., 2017, Dubey et al., 2019, Shah et al., 2019, Wong et al., 2014, Wong et al., 2019, de Miguel et al., 2017, Fung and Lang, 2020, Carneiro-Pla et al., 2014, Gambardella et al., 2020). Two papers (Amis et al., 2012, Kandil et al., 2016) were scored unclear for applicability concerns as they did not provide the diagnosis of participants. All ten swallowing studies, and all except one of the laryngeal studies scored as low for applicability concerns for choice of reference standard. Wong et al. (2014) scored high for applicability concerns as the GRBAS scale was self-rated by patients who provided their own perception of their voice difficulties, despite GRBAS only being validated for clinician assessment.

Summary of Study Findings

Oral phase studies of swallowing

The one identified study of oral phase swallowing function involved a small (n=9) population of patients with MND (Tamburrini et al., 2010). Five US parameters of tongue function were compared directly with VFSS measurements. These findings are described in table 1.

Studies of hyo-laryngeal movement

Four studies used US to assess hyo-laryngeal movement. Two measured hyo-laryngeal displacement as defined by the distance between the hyoid bone and mandible at rest and during swallowing (Chen et al., 2017, Lee et al., 2016), one measured the degree of approximation between the hyoid and larynx (Picelli et al., 2020) and the fourth measured geniohyoid contraction by assessing the percentage increase of coronal cross-sectional area (Cheng et al., 2018). Chen et al. (2017) found no significant differences between measurements of hyo-laryngeal displacement measured by US when compared directly with VFSS. The intra- and interrater reliability and intraclass correlation coefficient (ICC) of the two examiners was found to be excellent as was ICC between US and VFSS (see table 1).

Lee et al. (2016) used VFSS to estimate aspiration, penetration and residue status after swallowing to establish whether US measurements of hyo-laryngeal displacement can be used to clinically distinguish between clinical groups. Significant differences in hyoid displacement were found between patients with no residue and those with <10% residue and >10% residue ($p=0.0036$ and $p<0.001$ respectively). A value of 13.5mm was offered as a cut-off value to distinguish between non-aspirators and aspirators (sensitivity 83.9%, specificity 81.0%). Cheng

et al. (2017) found that percentage increase of geniohyoid cross sectional area correlated moderately with anterior ($r=0.42$, $p<0.05$) but not superior ($r=0.27$, $p=0.9$) hyoid displacement measured by VFSS in forty post-radiotherapy cancer patients.

Picelli et al. (2020) compared degree of hyoid-larynx approximation on US with the Gugging Swallow Screen (GUSS) and Functional Oral Intake Scale (FOIS). Significant differences in hyoid-laryngeal approximation were identified between n = 19 dysphagic (FOIS 1-6) versus non-dysphagic (FOIS 7) acute stroke patients. Direct associations were identified between hyoid-laryngeal approximation and FOIS and GUSS scores.

Studies of pharyngeal wall movement

Two studies measured US movement of the posterior pharyngeal wall in stroke (n=22) (Kim et al., 2012) and in a mixed (n=52) population (Manabe et al., 2018). Kim et al. (2012) measured lateral pharyngeal wall displacement of the weak side and compared this with three VFSS parameters described in table 1. In those that aspirated on VFSSS, pharyngeal wall displacement was found to correlate significantly with laryngeal elevation ($r=0.71$, $p = <0.047$), pharyngeal delay time ($r=-0.78$, $p=0.021$) and valleculae residue ($r=0.94$, $p<0.001$). No significant correlations were found between US and VFSS measurements in those that did not aspirate on VFSS.

Manabe et al. (2012) measured anterior movement of the posterior pharyngeal (cervical eosophageal - CE) wall and duration and velocity of CE wall opening and

closure on US. Significant positive correlations were found between duration of CE wall opening on US and duration of UES opening on VFSS ($r=0.86$, $p<0.001$).

Studies of Swallowing Symptoms

Three studies, all by the same group, assessed the utility of US to detect swallowing symptoms, specifically aspiration (Miura et al., 2014) and pharyngeal residue (Miura et al., 2016, Miura et al., 2020). Using a binary assessment of residue, Miura et al. (2016) found a 62% sensitivity and 67% specificity for use of US as a tool to diagnose residue which was defined as an 'area of high echogenicity' in the pyriform fossae and/or valleculae. Miura et al. (2020) used a more refined method of analysis and provided sensitivity and specificity measures using cut-off points (0, 5%, 10% and 50%) representing the percentage of a high echogenicity area. A 5% area of high echogenicity provided a superior 87.5% sensitivity (CI 86.9-95.5) and 78.1% specificity (CI 40.7-82.8) for diagnosis of pyriform fossae residues and 85% sensitivity (CI 73.4-92.9) and 81.8% specificity (CI 59.7-94.8) for diagnosis of valleculae residues. Detection of aspiration by US had a reported 64% sensitivity and 84% specificity when compared with a binary assessment of aspiration on combined VFSS and FEES assessment.

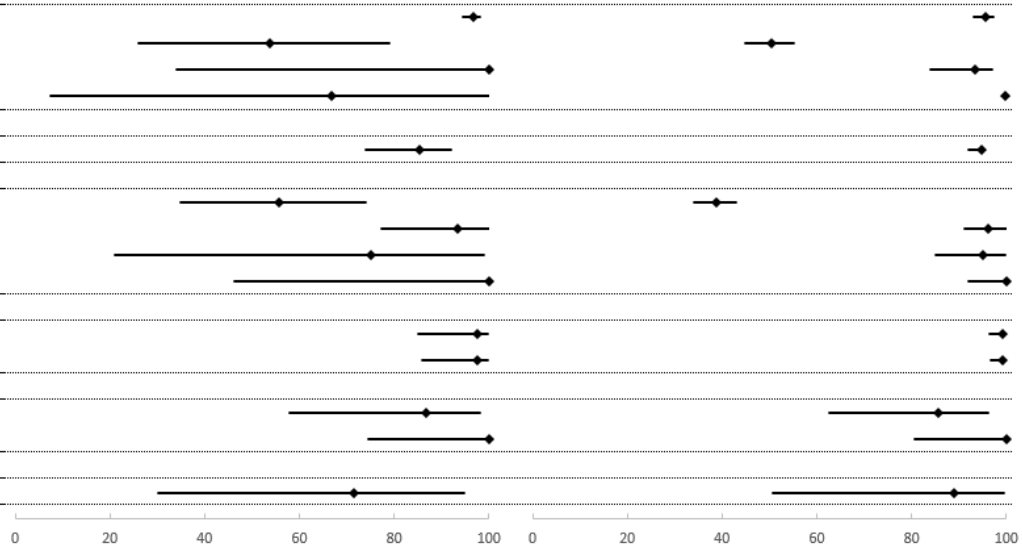
Studies of Laryngeal Function

Twelve papers compared combined pre-operative and post-operative sensitivity and specificity of US to measure vocal fold function compared to EEL. Figure 2 provides a visual overview of findings of included studies.

Sensitivity ranged from 64.3% (Kandil et al., 2016) to 100% (Kumar et al., 2018, Fung and Lang, 2020) and specificity from 48.5% (Kandil et al., 2016) to 100% (Kumar et al., 2018, Fung and Lang, 2020). Visualisation of vocal folds was reported in five studies and ranged from 49.1% (Kandil et al., 2016) to 100% (Fung and Lang, 2020). Figure 2 presents the sensitivity, specificity and confidence intervals for ten of the thirteen studies.

Figure 2: Graphical representation showing sensitivity, specificity, and confidence intervals of vocal fold studies

Pre-operative population	Sensitivity	Lower CI	Upper CI	Specificity	Lower CI	Upper CI
Gambardella et al 2020	96.8	94.4	98.2	95.6	93	97.3
Kandil et al 2016	53.8	26	79	50.5	45	55
Kumar et al 2016	100	34	100	93.4	84	97
Miguel et al 2017	66.7	7.4	100	100	99.4	100
Mixed pre-and post-operative population						
Wong et al 2019	85.3	74	92	94.7	92	95
Post-operative population						
Kandil et al 2016	55.6	35	74	38.7	34	43
Miguel et al 2017	93.3	77.3	100	96.1	91.2	100
Shah et al 2019	75	21	99	95.1	85.2	99.8
Fung et al 2020	100	46.3	100	100	92	100
Post-operative population high vs low frequency (MHz) ultrasound						
Woo et al 2017 (12-5MHz)	97.5	85	99.8	99.1	96.5	99.8
Woo et al 2017 (9-3 MH)	97.6	85.9	99.8	99.2	96.8	99.8
Post-operative population anterior vs lateral placement of ultrasound probe						
Kamel et al 2020 (anterior)	86.7	58	98	85.7	62.6	96.2
Kamel et al 2020 (posterior)	100	74.6	100	100	80.7	100
Mixed surgical and non-surgical population						
Amis et al 2012	71.4	30.2	94.8	88.9	50.7	99.4



Six studies reported positive predicted value (PPV) (true positives) and negative predictive value (NPV) (true negatives). PPV for US assessment ranged from 47.9% (Wong et al., 2019) to 100% (Fung and Lang, 2020). NPV for US assessment ranged from 22% (de Miguel et al., 2017) to 100% (Fung and Lang, 2020). In the six studies, NPV was higher than PPV in three studies (Wong et al., 2019, Shah et al., 2019, Gambardella et al., 2020), whilst PPV was higher than NPV in one study (de Miguel et al., 2017). In one study (Fung and Lang, 2020) both PPV and NPV were 100%, indicating perfect positive and negative screening accuracy. Study heterogeneity precluded meta-analysis or any other formal statistical analysis.

Three papers were not included in the data synthesis either due to lack of provision of raw data sets (Carneiro-Pla et al., 2014, Dubey et al., 2019) or differences in reference test (Wong et al., 2014).

Caneiro-Pla *et al*. (2014) achieved visualisation of the vocal folds in 668/887 patients (77%). Only 70/510 (13.7%) had both EEL and US assessment presenting high risk of bias. Of these, US correctly identified all seven cases with paralysed vocal folds. The sensitivity, specificity and overall accuracy of US in predicting fold paralysis was 100%, 98%, and 99%, respectively. Full data sets were not available to calculate confidence intervals. Dubey et al. (2018) performed correlation analysis of US versus EEL and found a high correlation ($r=0.93$, $p<0.001$) between vocal fold mobility combined with near perfect inter-rater agreement.

When comparing self-rated GRBAS scale with pre- and post-thyroidectomy US assessment of vocal fold asymmetry, Wong et al. (2014) found that participants with

vocal fold asymmetry rated themselves significantly higher on the GRBAS 'Grade' score (0.24 vs., 0.07, p=0.016) and 'Roughness' score (0.33 vs. 0.14, p=0.022) pre & post-operation, compared to those without asymmetry. Post-operative vocal fold asymmetry detected by US was associated with higher GRBAS scores.

Studies identified a number of factors associated with poorer US visualisation of the vocal folds. Age was found to affect US visualisation in two studies (Woo et al., 2017, Dubey et al., 2019), with poorer visualisation in older participants. Male gender was associated with poorer visualisation (51% compared to 82-96% in females) (Carneiro-Pla et al., 2014) and reduced US sensitivity and specificity identified in participants with a higher body mass index (BMI) (Kandil et al., 2016). BMI was also highlighted as a non-significant trend by (Fung and Lang, 2020) but not found to be a significant factor for visualisation by Carnierio–Pla et al. (2014). Use of low frequency US (3-9 MHz) was found to increase visualisation in one paper (Woo et al., 2017).

Discussion

This critical review aimed to establish the utility of US as an alternative tool to routine assessments such VFSS, FEES and/or EEL for the clinical assessment of swallowing and/or laryngeal function. The review was prompted by the COVID-19 pandemic, but the findings have the potential for application to many patient groups for management of laryngeal function or swallowing. This includes 'hard to reach' patient groups where challenges may exist in accessing VFSS, FEES and/or EEL due to geography and/or patient physical and cognitive limitations.

To our knowledge, this is the first comprehensive review of the literature examining the use of US in both swallowing and laryngeal function. We have examined 23 studies that compared US assessment of swallowing or laryngeal function with a standard reference test. All the studies demonstrated a practical ability to visualise structures and the biomechanics of swallowing and laryngeal function using US. However only two assessed more than one parameter within the same study (Tamburrini et al., 2010, Kamel et al., 2020). No study combined US assessment of laryngeal function with swallowing, despite the important function of the larynx in airway protection (Pitts, 2014).

Whilst there was homogeneity amongst laryngeal studies, in all but one (12/13), study, outcome measures were limited to the assessment of vocal fold function in a surgical population. Whilst this restricts the applicability of findings to SLT patients where more complex assessment of laryngeal function is required, the association of vocal fold palsy with glottal incompetence and aspiration (Bhattacharyya et al., 2002, Aneas et al., 2010, Zhou et al., 2018) supports its application to swallowing assessment using US.

Methodological heterogeneity of the swallowing studies prevented in-depth analysis and synthesis of findings. However, this narrative summary has allowed us to expand the findings of the review by Leite et al. (2014) progressing our understanding of US as a diagnostic tool for dysphagia and to make future recommendations for application by SLTs.

Swallowing & Laryngeal Studies

All studies of swallowing biomechanics identified an association or statistical relationships between one or more parameters measured by US compared to VFSS or FEES (Tamburrini et al., 2010, Chen et al., 2017, Cheng et al., 2018, Kim et al., 2012, Manabe et al., 2018) or between US parameters and clinical surrogates for dysphagia, such as residue, aspiration or restriction in oral intake (Lee et al., 2016, Picelli et al., 2020). The lack of direct biomechanical relationship between US and VFSS parameters measured by Kim et al. (2012) may explain why US measures did not correlate in the group of non-aspirators. The challenges of visualising areas of high echogenicity instead of anatomical structure and movement may explain the low (<65%) sensitivity of US to detect residue and aspiration (Miura et al., 2014, Miura et al., 2016). A more refined method of analysis was used in the later study (Miura et al., 2020) leading to a higher (85%) sensitivity.

There is currently no standardised protocol or reference test for US assessment of swallowing. Whilst some studies compare a physiological parameter with the equivalent measure on VFSS and/or FEES imaging, others use surrogate measures for dysphagia such as ratings of residue, aspiration and oral intake scales. The most frequently utilised parameter for US swallowing assessment was hyoid displacement with agreement of measurement amongst included studies (Chen et al., 2017, Lee et al., 2016) and existing literature (Chi-Fishman and Sonies, 2002, Yabunaka et al., 2011, Hsiao et al., 2012).

Laryngeal assessment focused on vocal fold mobility rather than other aspects of the larynx, for example arytenoid tilt or vocal fold structure. This simplicity, plus a more

standardised approach to assessment amongst pre-existing laryngeal assessment tools may part-explain the reasons for the increased homogeneity.

The sensitivity of US to diagnose vocal fold impairment ranged between 63.4-100% with a tendency for wide confidence intervals. These figures suggest that the clinical application of US may be best suited as a first-line non-invasive tool to rule out rather than rule-in issues with vocal fold mobility. This would correspond with the use of US in other clinical areas (Stengel et al., 2018, You-Ten et al., 2018).

Kandil et al. (2016) had much lower sensitivity and specificity figures than other included studies. This study used a static (12MHz) frequency probe rather than a spectrum of frequencies (for example, 6-13MHz). Lower frequencies are understood to penetrate the larynx more easily allowing for better visualization of structures (Ng and Swanevelder, 2011). This was also identified by studies included in the review (Woo et al., 2017). The authors propose that participant BMI affected visualisation. This is consistent with studies that have associated high BMI with lower quality US images (Brahee et al., 2013). Altered body composition may also account for differences in visualisation across age (Woo et al., 2017, Dubey et al., 2019) and gender (Carneiro-Pla et al., 2014). Clinicians should be mindful of these challenges when interpreting US findings in these cohorts of patients.

Reference Tests

Studies in this review applied a wide range of reference tests. Whilst protocols for these tests were routinely defined, there was poor standardisation across studies and infrequent reference to inter and intra-rater reliability. Absence of reliability

reporting is problematic as differences in identification between reference test and US could be considered a simple error. Future studies should use the available standardised and validated scales (Martin-Harris et al., 2008, Rosenbek et al., 1996, Neubauer et al., 2015).

Clinical Utility of Ultrasound for Swallowing and Laryngeal Assessment

This review has shown that US as a tool for comprehensive swallowing assessment is not currently indicated for use within SLT. However, it does have an emerging role as an assessment of specific structures related to swallowing, including vocal fold mobility. This offers clinical potential as an adjunctive tool. Its role as a complement rather than as a substitute to standard assessments is acknowledged in the wider literature (Fatima et al., 2015, Chung and Kim, 2015). The unique capability of US to evaluate muscle structure and understand underlying pathology also supports its utility as a supplementary tool (Van Den Engel-Hoek et al., 2017).

The absence of protocols in the current literature has impacted on the quality and transferability of the evidence from this review. An important consideration for SLTs is the need for structured training and validated tools in the application and analysis of US findings. Future research is required to promote a standardised approach, including reliability of interpretation and the wider adoption of any tool.

Below we outline some considerations for developing SLT-led protocols and future research studies:

- Visualisation and interpretation: Both are operator dependent and require competency development (Pinto et al., 2013, Todsen et al., 2015, Todsen et al., 2018). A major limitation of the included studies was the use of a single-operator design and absent reliability assessment. This limits the reproducibility of the results and may be another explanation for outlying sensitivity and specificity data within the laryngeal studies.

- Equipment: Selection of US machine, probe and frequency varied greatly in this review. Other clinical areas have acknowledged potential for variation (Aldrich, 2007) and have highlighted the need for consensus guidelines, for example within thyroid assessment (Rago et al., 2018). Our review demonstrates that US will need clear standard operating procedures for SLTs to use it as a clinical tool.

- Normative data: The lack of normative data for either vocal fold movement or measurements of structures as a surrogate for swallowing is problematic. Some studies have provided normative values (Miller and Watkin, 1997). To identify clinical concern during an US assessment, normative values are necessary.

Strengths and limitations of the review

Multiple individuals participated in the data extraction and quality assessment of this review, increasing potential for inter-rater differences. To minimise differences

methodological safeguards were put in place. These were achieved by developing strict inclusion/exclusion criteria, re-assessing a random sample of abstracts, piloting of the data extraction form and group discussion of full text papers, as well as clear written guidelines for the QUADAS-2 assessment.

Due to the pace and context, the team were unable to register the review or publish a formal protocol. Furthermore, as there was no funding attached to the project the remit of the review did not extend to any formal quantitative or meta-analysis. The speed of the review also restricted engagement with patient and public stakeholders who would have been ideally placed to co-develop methodology and provide a unique perspective on the findings. Future research in this area should prioritise the patient perspective of assessment using this tool.

A rapid review methodology was chosen to disseminate findings as quickly as practicable to clinicians globally within the context of the COVID-19 pandemic. Only studies published in English since 2010 were included. Restricting language and date limits may mean that some important studies could have been missed. Extending dates may however have increased variability of findings particularly as US technology has evolved. We had no resources to include studies in other languages.

Future Directions

This rapid review ignited enthusiasm to progress the clinical application of US through the development of SLT protocols for swallowing and laryngeal assessment in the future. This would optimally be combined with devising a training

program for SLTs to conduct US assessment. This should include the identification of key clinical landmarks, static versus dynamic assessment, what equipment to use and the technical aspects of operating ultrasonography equipment. Furthermore, work to establish and improve inter-rater reliability for key assessment parameters is an important goal for future work in this area.

Summary and Conclusion

There is emerging evidence to support the utility of US as an adjunct clinical tool for the assessment of swallowing and laryngeal function. Further studies are warranted in a wider range of clinical populations and clinical settings, with increased attention to the enhancement of sensitivity and specificity measures yielded using US. Based on this review, US is currently not recommended as a tool to use in isolation but its potential as a supplementary tool for swallowing and laryngeal assessment is acknowledged. This rapid review has led to an international collaboration that will promote future, targeted research to develop US into a robust and functional clinical tool for use in the management of patients with swallowing and laryngeal difficulties.

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