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CLINICAL EVALUATION OF SWALLOWING

Jonna Kuuskoski



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To my family
Amoto quaeramus seria ludo

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ABSTRACT

Swallowing difficulty, or dysphagia, is a common symptom resulting from aging, disease, or stress-related mechanisms (functional dysphagia). Dysphagia affects physical and mental health, quality of life, and social interactions. If left untreated, it can lead to serious complications such as malnutrition, dehydration, and aspiration pneumonia. However, many individuals fail to recognize their condition.

The diagnosis of dysphagia relies on a patient's medical history, clinical examination, and diagnostic tests such as videofluoroscopy (VFS) or flexible endoscopic evaluation of swallowing (FEES). Because swallowing is a complex process, benign symptoms unrelated to disease can occur. This condition, known as functional dysphagia, is as debilitating and costly as organic dysphagia.

This dissertation aimed to translate and validate the Finnish version of the Eating Assessment Tool (EAT-10) for assessing swallowing symptoms and to evaluate the effectiveness of EAT-10 and the water swallow test (WST) in determining the need for VFS. The Finnish EAT-10 proved to be a valid, reliable tool for diagnosing and monitoring dysphagia. The WST was more effective than EAT-10 in identifying patients who would benefit from VFS. Reliability analyses of VFS assessments revealed the strongest agreements in evaluating pharyngeal residues and penetration-aspiration findings. The clinical significance of objective measurements remained unclear.

This study also examined the impact of FEES with swallowing guidance on dysphagia. The results showed notable benefits, particularly for patients with functional dysphagia, as early as the first month. These findings highlight the importance of early intervention for this group, for whom extensive diagnostic testing may not be necessary.

This research refines dysphagia assessment and diagnostic protocols, introduces the validated Finnish EAT-10 questionnaire, and emphasizes targeted use of diagnostic tools like VFS and FEES. It provides valuable insights to improve patient outcomes, reduce healthcare costs, and optimize resource use in managing dysphagia.

KEYWORDS: swallowing, dysphagia assessment, dysphagia evaluation, functional dysphagia, water swallow test, videofluoroscopy, EAT-10

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TIIVISTELMÄ

Nielemisvaikeus eli dysfagia on yleinen oire, joka johtuu ikääntymisestä, sairauksista tai stressiin liittyvistä mekanismeista (toiminnallinen dysfagia). Dysfagia vaikuttaa fyysiseen ja psyykkiseen terveyteen, elämänlaatuun ja sosiaalisiin suhteisiin. Hoitamattomana se voi aiheuttaa vakavia komplikaatioita, kuten aliravitsemusta, kuivumista ja aspiraatiopneumoniaa. Toisaalta nielemisvaikeus voi jäädä myös tunnistamatta.

Nielemisvaikeuden diagnostiikka perustuu esitietoihin, kliiniseen tutkimukseen ja tarvittaessa jatkotutkimuksiin kuten videofluoroscopiaan (VFS) tai nielemisen tähytystutkimukseen (FEES). Koska nieleminen on monimutkainen tapahtumasarja, siinä voi ilmetä hyvänlaatuisia, sairauteen liittymättömiä oireita. Toiminnallinen dysfagia heikentää elämänlaatua ja aiheuttaa terveydenhuollon kustannuksia vastaavasti kuin elimellinenkin nielemisvaikeus.

Väitöskirjatyön tavoitteena oli suomentaa ja validoida käyttöön nielemisen oirekysely Eating Assessment Tool, EAT-10, sekä arvioida sen ja vesitestin käyttökelpoisuutta VFS:n tarveharkinnassa. Suomenkielinen EAT-10 osoittautui validiksi ja luotettavaksi työkaluksi dysfagian arvioinnissa ja seurannassa. Vesitesti puolestaan osoittautui käyttökelpoisemmaksi VFS-tutkimuksesta hyötyvien potilaiden tunnistamisessa. VFS:n reliabiliteettianalyysit osoittivat vahvimmat yhteneväisyydet nielun residuaalien ja penetraatio-aspiraatiolöydösten arvioinnissa. Objektivisten mittausten kliininen merkitys jäi epäselväksi.

Tutkimuksessa tarkasteltiin myös FEES-tutkimuksen ja nielemisohjauksen vaikutuksia. Tutkimuksessa havaittiin kertaluontoisen nielemisohjauksen hyödyttävän erityisesti toiminnallisesta dysfagiasta kärsiviä potilaita jo ensimmäisen kuukauden aikana. Havainnot korostavat varhaisen intervention merkitystä näille potilaille, joille laajat diagnostiset tutkimukset eivät välttämättä ole tarpeen.

Tutkimus tarkentaa nielemisvaikeuden arviointi- ja tutkimusprotokollia, esittelee validoidun suomalaisen EAT-10-kyselyn ja painottaa diagnostisten työkalujen kohdennettua käyttöä. Tämä väitöskirja tarjoaa arvokkaita näkökulmia potilaiden hoitotulosten parantamiseen, terveydenhuollon kustannusten vähentämiseen ja resurssien tehokkaaseen hyödyntämiseen dysfagian hoidossa.

AVAINSANAT: nieleminen, nielemisvaikeuden arviointi, nielemisvaikeuden tutkiminen, toiminnallinen nielemisvaikeus, vesitesti, videofluoroscopia, EAT-10

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Abbreviations

15D	15D Health-Related Quality of Life Instrument
ACD	Airway closure duration
Air Kerma	Kinetic energy released per unit mass of air by radiation
ALARA	As low as reasonably achievable
ALS	Amyotrophic lateral sclerosis
BDST	Burke Dysphagia Screening Test
BMI	Body Mass Index
BSE	Bedside swallowing evaluation
CBT	Cognitive behavioural therapy
CEM	Circular oesophageal muscle
CI	Confidence interval
CPM	Cricopharyngeal muscle
DAP	Dose Area Product
DHI	Dysphagia Handicap Index
DIGEST	Dynamic Imaging Grade of Swallowing Toxicity
DOSS	Dysphagia Outcome Severity Scale
DYMUS	Dysphagia in multiple sclerosis
EAT-10	Eating Assessment Tool
EGD	Esophagogastroduodenoscopy
ENT	Ear, nose, and throat
EoE	Eosinophilic esophagitis
ESSD	European Society for Swallowing Disorders
FEES	Fiberoptic/Flexible endoscopic evaluation of swallowing
FEES	Fiberoptic endoscopic examination of swallowing safety
GERD	Gastroesophageal reflux disease
GLUPS	Group for Learning Useful and Performant Swallowing
GUSS	Gugging Swallowing Screen
HEMII-pH	Hypopharyngeal-oesophageal multichannel intraluminal impedance-pH monitoring
HNC	Head and neck cancer
HRM	High-resolution oesophageal manometry

HRQoL	Health-related quality of life
ICC	Intraclass correlation coefficient
ICD	International Classification of Diseases
ICF	International Classification of Functioning, Disability, and Health
IDDSI	International Dysphagia Diet Standardisation Initiative Framework
IOPI	Iowa Oral Performance Instrument
IPC	Inferior pharyngeal constrictor
KJ	Killian-Jamieson diverticulum
LAD	Lateral diverticulum
LD	Laimer's diverticulum
LEM	Longitudinal oesophageal muscle
LES	Lower oesophageal sphincter
LPR	Laryngopharyngeal reflux
LPRD	Laryngopharyngeal reflux disease
LR	Likelihood ratio
MADS	Measure of achalasia severity
MASA	Mann Assessment of Swallowing Ability
MBSImp	Modified Barium Swallow Impairment Profile
MDADI	MD Anderson Dysphagia Inventory
MII-pH	Multichannel intraluminal impedance-pH monitoring
MMASA	Modified Mann Assessment of Swallowing Ability
MS	Multiple sclerosis
NBI	Narrow band imaging
PACS	Picture Archiving and Communication System
PAhold	Pharyngeal aerated area during bolus holding
PAm _{ax}	Maximum pharyngeal area during swallowing
PAS	Penetration-Aspiration Scale
PCR	Pharyngeal constriction ratio
PEG	Percutaneous endoscopic gastrostomy
PES	Pharyngoesophageal segment
PES _{max}	Maximum pharyngoesophageal segment opening
P-HRM	High-resolution pharyngeal manometry
P-HRM-I	P-HRM including impedance
POD	Pharyngoesophageal segment opening duration
POEM	Peroral endoscopic myotomy
PROM	Patient-reported outcome measure
R-CPD	Retrograde cricopharyngeus dysfunction
RLN	Recurrent laryngeal nerve
SD	Standard deviation
SLP	Speech and language pathologist

SOAL	Swallowing Outcome after Laryngectomy
SS	Swallowing speed
SVE	Swallow Video Endoscopy
SWAL-QOL	Swallowing Quality of Life Questionnaire
sWST	Simplified Water Swallow Test
TNE	Transnasal oesophagoscopy
TOMASS	Test of Masticating and Swallowing Solids
TOR-BSST	Toronto Bedside Swallowing screening test
TPT	Total pharyngeal transit time
UES	Upper oesophageal sphincter
VEED	Videoscopic evaluation of dysphagia
VFS	Videofluoroscopy
V-VST	Volume-viscosity swallowing test
WHO	World Health Organization
WHODAS 2.0	WHO Disability Assessment Schedule
WST	Water swallow test
ZD	Zenker's diverticulum

List of Original Publications

This dissertation is based on the following original publications, which are referred to in the text by their Roman numerals:

- I Järvenpää P, Kuuskoski J, Pietarinen P, Markkanen-Leppänen M, Freiberg H, Ruuskanen M, Rekola J, Ilmarinen T, Kinnari TJ, Autio TJ, Penttilä E, Mutttilainen MS, Laaksonen A, Oksanen L, Geneid A, Aaltonen LM. Finnish Version of the Eating Assessment Tool (F-EAT-10): A Valid and Reliable Patient-reported Outcome Measure for Dysphagia Evaluation. *Dysphagia*, 2022; 37(4):995-1007.
- II Kuuskoski J, Vanhatalo J, Rekola J, Aaltonen LM, Järvenpää P. The Water Swallow Test and EAT-10 as Screening Tools for Referral to Videofluoroscopy. *Laryngoscope*, 2024; 134(3):1349-1355.
- III Kuuskoski J, Vanhatalo J, Hirvonen J, Rekola J, Aaltonen LM, Järvenpää P. Inter-rater reliability and clinical relevance of subjective and objective interpretation of videofluoroscopy findings. *Laryngoscope Investig Otolaryngol*, 2024; 3:9(4):e1298.
- IV Kuuskoski J, Rekola J, Sintonen H, Aaltonen LM, Järvenpää P. Swallowing guidance with FEES may alleviate symptoms in functional dysphagia. Manuscript.

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1 Introduction

Dysphagia, or difficulty swallowing, is a common symptom associated with various diseases. It is especially prevalent among the elderly and patients with neurological conditions (Clavé & Shaker, 2015; Lindgren & Janzon, 1991; Meng et al., 2000). As the population ages, the prevalence of dysphagia is increasing (Baijens et al., 2016; Clavé et al., 2012). Dysphagia has significant physical, psychological, and social consequences, often leading to complications such as aspiration pneumonia, dehydration, malnutrition, and higher healthcare costs (Ekberg et al., 2002; Rofes et al., 2011; Wilson, 2012). Despite these risks, many individuals remain unaware of their condition. Therefore, it is crucial to raise awareness about dysphagia and enhance understanding of its diagnostic methods and treatment options, both within the medical field and among the general public (Ekberg et al., 2002).

Swallowing is a complex process involving coordinated movements, primarily controlled by the parasympathetic vagus nerve. Disturbances in swallowing can occur without any underlying physical disease (Baijens et al., 2013). Patients with this type of ‘non-organic dysphagia’ or functional dysphagia benefit from clear explanation and validation of their condition, as further examinations and referrals may reinforce unhelpful illness behaviour and symptom interpretation (Deary et al., 2007). Therefore, it is crucial to differentiate benign, functional dysphagia from more serious organic causes.

Swallowing consists of three phases: oral, pharyngeal, and oesophageal, and identifying the affected phase is key to an accurate diagnosis. Up to 80% of dysphagia cases can be diagnosed through a detailed medical history, with additional instrumental examinations such as videofluoroscopy (VFS), flexible endoscopic evaluation of swallowing (FEES), and oesophageal manometry, providing further insights when necessary (Spieker, 2000).

Dysphagia assessment and management vary across healthcare settings, from emergency care to home services. Effective screening and monitoring tools, such as the Eating Assessment Tool (EAT-10) and water swallow tests (WSTs), are useful for evaluating symptom severity and treatment outcomes (Belafsky et al., 2008; Brodsky et al., 2016). Although EAT-10 has been validated internationally, it has yet to be assessed in Finnish. Health-related quality of life (HRQoL) measures, like the 15D instrument, are also valuable for assessing health outcomes (Sintonen, 2001).

Several methods exist for assessing dysphagia, with VFS and FEES considered the gold standards. However, VFS lacks standardization in many institutes. Various

rating methods, such as the Videofluoroscopic Dysphagia Scale and Group for Learning Useful and Performant Swallowing (GLUPS), have been developed, though their inter-rater reliability can be inconsistent (Lechien, Cavelier, et al., 2019; McCullough et al., 2001; Scott et al., 1998). Objective measurement methods, like those proposed by Kendall and Leonard, offer more consistent evaluations, but they are time-consuming and have not yet been widely adopted (Kendall, 2000; Leonard et al., 2000).

Swallowing is a complex physiological process, and benign, non-disease-related symptoms are common, many of which may improve or resolve spontaneously over time (Nevalainen et al., 2016). Therefore, it is essential to identify accurate but feasible methods for distinguishing patients who would benefit from resource-intensive diagnostic assessments from those for whom such interventions are unnecessary.

2 Review of the Literature

2.1 Anatomy and physiology of normal swallowing

Swallowing, or deglutition, is a complex process that involves multiple structures in the mouth, throat, and oesophagus working together to move food and liquids from the mouth to the stomach. The swallowing process can be divided into three phases: the oral phase, the pharyngeal phase, and the oesophageal phase (Figure 1).

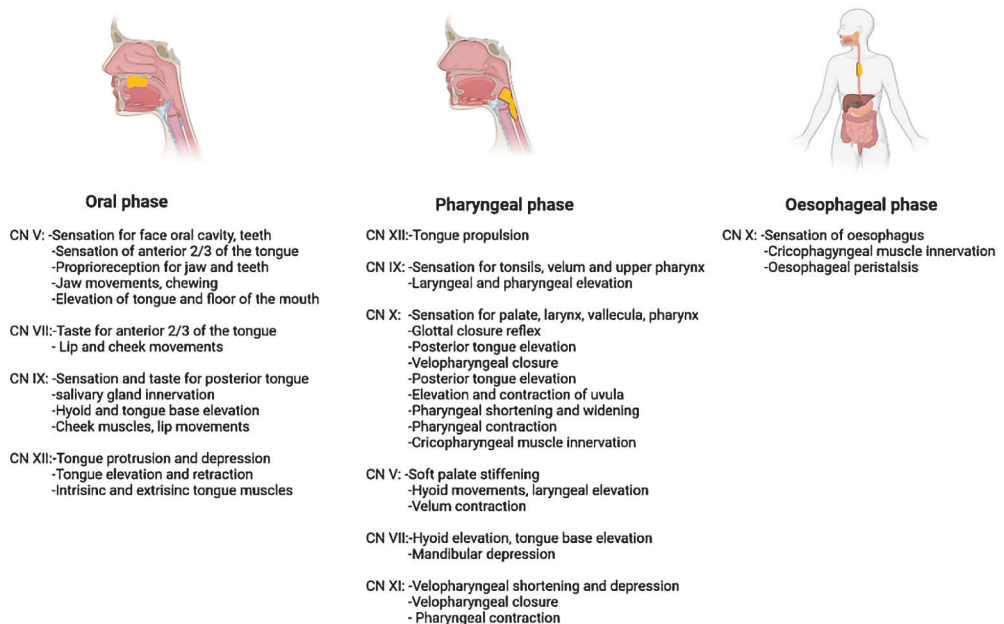


Figure 1. The phases of swallowing and the cranial nerves (CN) involved in the swallowing process. Image created in BioRender: Kuuskoski J. (2024) *BioRender.com/h36x097*

The oral phase initiates swallowing: food is prepared in the mouth and then moved toward the back of the throat. This phase is under voluntary control. Mastication, or chewing, is part of the preparatory oral phase. During mastication, the teeth and jaws mince the food while the salivary glands produce saliva. The

tongue gathers the food and mixes it with saliva, forming a soft mass called the bolus. The tongue then forms a cup-like shape in the centre of the mouth, pressing the bolus against the hard palate to prepare for the next stage. This latter part of the oral phase is referred to as the propulsive oral phase. The oral phase ensures that food is properly prepared and manageable for safe swallowing (Mankekar, 2015; Matsuo & Palmer, 2008).

When the bolus reaches the posterior part of the mouth and touches the back of the tongue and the pharynx, it triggers the swallowing reflex. This marks the transition from the voluntary oral phase to the involuntary pharyngeal phase.

Pharyngeal phase involves rapid, coordinated reflexive actions that help safely transport the bolus from the mouth into the oesophagus, bypassing the airway. As the tongue moves the bolus to the back of the mouth, it triggers the elevation of the soft palate (velum), which blocks the nasal passage (nasopharynx) to prevent food or liquid from entering the nose during swallowing. The larynx moves upward and forward, helping to close off the airway (trachea) and prevent penetration (the entry of food or liquid into the larynx while remaining above the vocal cords) and aspiration (the entry of food or liquid into the trachea).

The epiglottis, a flap-like cartilage, folds backwards to cover the larynx. Inside the larynx, the vocal cords and vestibular folds constrict the laryngeal aperture, protecting the airway as the bolus passes through the pharynx via the lateral canals. The base of the tongue, together with the pharyngeal muscles, contracts to push the bolus downward in a piston-like manner, opening the upper oesophageal sphincter (UES) and allowing the bolus to enter the oesophagus (McConnel, 1988; McConnel et al., 1988).

The end of the pharyngeal phase is determined when the soft palate returns to its original position and the larynx reopens for respiration (Leonard & Kendall, 2017). The oral and pharyngeal phase are often combined in definitions as the oropharyngeal phase.

The oesophageal phase is also involuntary and involves the transport of the bolus from the pharynx to the stomach via the oesophagus. The muscular valves, known as the upper and lower oesophageal sphincters, control the entry and exit of the bolus into and out of the oesophagus. The UES remains closed at rest due to the tonic contraction of the cricopharyngeal muscle (CPM). Anterior laryngeal traction, CPM relaxation, and pressure from the bolus generated by the laryngeal muscles open the UES, allowing the bolus to pass into the oesophagus (Cook et al., 1989).

Manometric studies indicate that a successful pharyngeal swallow relies more on the pressure created by effective tongue movements and the negative pressure developed by pharyngoesophageal segment (PES) than on the actual peristalsis of the pharyngeal constrictors (McConnel, 1988; McConnel et al., 1988). After entering the oesophagus, a series of wave-like muscle contractions known as peristalsis

moves the bolus downward with the help of gravity. The lower oesophageal sphincter (LES) relaxes to allow the bolus to pass into the stomach, then contracts to prevent stomach contents from refluxing back into the oesophagus, thus ending the oesophageal phase of swallowing (Shaker et al., 2013). The UES opening can be considered part of both the pharyngeal and oesophageal phases (Leonard & Kendall, 2017; Mankekar, 2015; Shaker et al., 2013). In this thesis, the latter division is used.

Swallowing is a complex series of movements that involves activation and inhibition of more than 25 pairs of muscles in the mouth, pharynx, larynx and oesophagus, controlled by central pattern-generating circuitry of the cortical structures, cerebellum, basal ganglia, brainstem and peripheral reflexes (Kaji & Murase, 2001; Lang, 2009; Mosier & Bereznya, 2001; Suzuki et al., 2003). Although the different phases of swallowing are independent of each other, they interact via excitatory and inhibitory feedback signals. The brainstem also regulates and coordinates the timing of breathing and swallowing, which is crucial for airway protection (Lang, 2009).

2.2 Dysphagia

2.2.1 Definition and prevalence

Dysphagia comes from the Greek words "dys", meaning "difficulty" or "disorder", and "phago", meaning "to eat" or "swallow". According to the International Classification of Functioning, Disability, and Health (ICF, code b5105), endorsed by the World Health Organization (WHO), swallowing is described as “Functions of clearing substances, such as food, drink and saliva through the oral cavity, pharynx and oesophagus into the stomach at an appropriate rate and speed” (*WHO. International Classification of Functioning, Disability and Health*, 2024) In the International Classification of Diseases, also supported by WHO (ICD-11 code MD93, ICD-10 code R13) dysphagia is categorized under "Symptoms or signs involving the digestive system or abdomen” (*ICD-10*, 2019; *ICD-11*, 2024). It is important to recognize that dysphagia is a symptom, not a disease.

Problems can occur at any stage of swallowing, from moving food or liquid from the mouth to the stomach. Symptoms vary but typically include food sticking in the throat or chest, pain or distress while swallowing, and choking or coughing when eating or drinking. Dysphagia is usually classified according to the swallowing phase into two main types: oropharyngeal or oesophageal dysphagia. It can be caused by a variety of factors and can also be classified according to aetiology into organic or non-organic (or functional) dysphagia.

Dysphagia is relatively common and affects approximately 20% of the general population (Lindgren & Janzon, 1991). The prevalence of dysphagia increases with

age and is related to many diseases. Among individuals over 80 years old who live independently, the prevalence is 33%, and half of hospitalised patients suffer from dysphagia (Bloem et al., 1990; Clavé et al., 2012; Clavé & Shaker, 2015). Many neurological diseases disrupt normal swallowing, and more than 80% of patients with acute stroke have been reported to have dysphagia (Meng et al., 2000). Among young and middle-aged adults, oesophageal and functional dysphagia are more common aetiologies (Baijens et al., 2013; Lindgren & Janzon, 1991). The true prevalence of dysphagia may be even higher because it is often unreported by patients and unrecognized by clinicians (Ekberg et al., 2002; Rofes et al., 2011).

Dysphagia can lead to serious effects, such as severe nutritional and respiratory complications, dehydration, social isolation, mental health problems, and even death (Ekberg et al., 2002). It also results in significant healthcare expenses (Wilson, 2012). Conversely, it is relatively common for individuals to experience discomfort or a sensation of difficulty swallowing without any organic cause (Baijens et al., 2013; Verdonschot et al., 2019).

2.2.2 Aetiology and symptoms

2.2.2.1 Oral dysphagia

Oral dysphagia refers to difficulty swallowing that originates in the mouth (oral cavity). It occurs during the oral phase of swallowing, where difficulties in mastication, forming a bolus, or moving the bolus towards the pharynx can impair the swallowing process. This type of dysphagia is typically caused by problems with the muscles or nerves that control the mouth and tongue (Sawczuk & Mosier, 2001). Common causes of oral dysphagia include neurological or structural issues. Paresis or paralysis of the seventh cranial nerve, such as in Bell's palsy, can weaken the oral closure, affect the sense of taste in the front two-thirds of the tongue, and impair saliva production. Neurologic diseases such as stroke, Parkinson's disease, multiple sclerosis (MS), and amyotrophic lateral sclerosis (ALS) can impair control over tongue and mouth movements (Andersen et al., 2012; Meng et al., 2000; Mirmosayyeb et al., 2023; Pflug et al., 2018; Ruoppolo et al., 2013). Muscular dystrophy or myasthenia gravis can weaken the masticatory and oral muscles (Stathopoulos & Dalakas, 2022; Toussaint et al., 2016). Missing teeth, cavities or poorly fitting dentures can make chewing painful or ineffective. Dry mouth (xerostomia) can also make it difficult to form and move the bolus effectively (Stoopler et al., 2024; Tanasiewicz et al., 2016). Oral mucosal diseases, such as acute stomatitis, lichen planus, oral candidiasis, recurrent aphthous stomatitis, bullous diseases, and proliferative verrucous leucoplakia, as well as tumours in the oral cavity, can affect bolus transit (Jascholt et al., 2017; Stoopler et al., 2024; Thompson

et al., 2021). Psychological issues or eating disorders can create fear or aversion to swallowing (Baijens et al., 2013; McNally, 1994).

Symptoms of oral dysphagia include difficulty of chewing food properly, inability to form a cohesive bolus, prolonged masticatory and oral transit time, food or liquid leaking from the mouth (spillage), difficulty controlling the bolus in the mouth, trouble moving the bolus to the back of the mouth, and frequent coughing or choking during eating or drinking (due to penetration or aspiration, or posterior spillage).

2.2.2.2 Pharyngeal dysphagia

Pharyngeal dysphagia refers to difficulty swallowing that occurs during the pharyngeal phase of swallowing. The swallowing reflex may be absent or delayed, or structural issues may impair the transmission of the bolus from the mouth to the oesophagus. Aetiologies can include neurological disorders, muscle weakness, structural abnormalities, or aging-related changes. Tumours, infections, and foreign bodies can also cause swallowing difficulties in pharyngeal phase.

Symptoms of pharyngeal dysphagia may manifest as coughing or choking while eating or drinking, regurgitation of food or liquids (sometimes even through the nose), a sensation of food sticking in the throat, frequent throat clearing or wet-hoarse voice after swallowing, aspiration (which may lead to recurrent pneumonia or respiratory infections), and difficulty swallowing liquids and/or solids.

2.2.2.3 Oropharyngeal dysphagia

Oral and pharyngeal dysphagia are often referred to as oropharyngeal dysphagia. As mentioned above, stroke is one of the most common causes of oropharyngeal dysphagia, particularly strokes involving the cerebral, cerebellar, and brain stem areas (Martino et al., 2005; Meng et al., 2000). Other neurological diseases, such as Parkinson's disease, myasthenia gravis and amyotrophic lateral sclerosis, often impair the safety and efficacy of oropharyngeal swallowing (Owolabi et al., 2014; Petit et al., 2012; Rajaei et al., 2015; Tabor et al., 2016). Neurodegenerative diseases, like Alzheimer's disease, may lead to various difficulties, including food pocketing in the mouth, mastication problems, coughing or choking on food or fluid, the need of reminders to swallow, visual recognition difficulties, oral-tactile agnosia, and swallowing and feeding apraxia (Alagiakrishnan et al., 2013; Priefer & Robbins, 1997).

Pharyngeal phase impairment can result in aspiration pneumonia occurring before, during, and after swallowing (Finucane et al., 1999). Dysphagia may also be associated with many medications, especially neuroleptic drugs and benzodiazepines

(Ebadi et al., 1990; Miarons Font & Rofes Salsench, 2017). Additionally, tumours, surgery, or trauma to the head and neck, chest, brain, or spinal areas can lead to dysphagia due to nerve injury or brain damage (Kuhn et al., 2023; Miles et al., 2021; Nachalon, 2022; Park et al., 2023; Plowman et al., 2023; Takizawa et al., 2016). It is also common for critically ill and mechanically ventilated patients to experience dysphagia after intubation (Brodsky et al., 2020; Frajkova et al., 2020; Macht et al., 2011; Schefold et al., 2017).

It is crucial to differentiate dysphagia from globus sensation, which is the feeling of a foreign object or a lump in the throat, typically more noticeable when swallowing saliva or during “dry” swallows. This sensation is often relieved by swallowing food or liquids. (Galmiche et al., 2006). Laryngopharyngeal reflux (LPR) refers to inflammation in the pharynx or nasopharynx due to gas or liquid reflux from the stomach (Lechien, Saussez, et al., 2019). Symptoms of LPR typically include more globus sensation and odynophagia (painful swallowing) than actual dysphagia, along with hoarseness, postnasal drip, and sticky mucus in the throat. (Lechien, Akst, et al., 2019).

When evaluating symptoms, it is crucial to recognize that dysphagia and odynophagia are common among cancer patients, affecting not only those with head and neck cancers but also individuals with other malignancies (Raber-Durlacher et al., 2012). Dysphagia may arise prior to diagnosis as a direct result of tumour effects or develop as a consequence of cancer treatments, including surgery, chemotherapy, radiotherapy, and other modalities like epidermal growth factor receptor inhibitors (Logemann et al., 2006; Nguyen et al., 2004; Pauloski et al., 2000; Pryor et al., 2009; Raber-Durlacher et al., 2012; Wirth et al., 2010). Furthermore, the presence of dysphagia before initiating chemoradiation for head and neck cancer is an independent predictor of post-treatment swallowing difficulties (Cates et al., 2022). Additional oral complications, such as xerostomia, can exacerbate the perception of dysphagia (Hamlet et al., 1997). Chemoradiation may also lead to long-term swallowing impairments. For instance, in p16+ oropharyngeal squamous cell carcinoma patients treated with definitive chemoradiation, at least 7.5% developed late progressive dysphagia, while 15.1% experienced moderate dysphagia persisting more than 2.5 years after treatment (Gharzai et al., 2020).

2.2.2.4 Upper oesophageal sphincter

The UES, also known as the PES or pharyngoesophageal junction, is a high-pressure zone measuring 2.5-4.5 cm located at the junction between the pharynx and oesophagus, just below the larynx and in front of the cervical spine (Belafsky et al., 2010; Cook et al., 1992; Ferreira et al., 2008). It primarily consists of the 1–2 cm long, c-shaped cricopharyngeal muscle (CPM), which is anchored to the cricoid

cartilage. The CPM wraps around the upper cervical oesophagus posteriorly and is part of the inferior constrictor muscles. The UES also includes fibres from the cervical oesophagus and the thyropharyngeal muscle, forming part of the inferior constrictor block.

In its resting state, the UES is typically closed due to tonic contraction, which prevents air from entering the oesophagus during respiration. The UES relaxes momentarily during swallowing to allow the passage of food and liquid into the oesophagus. Once the bolus passes, the UES contracts again to prevent backflow (regurgitation) into the pharynx. UES relaxation is also necessary during belching or vomiting. The process of UES relaxation can be divided into five stages: 1) Inhibition of tonic contraction in the CPM. 2) Elevation and anterior movement of the larynx due to contraction of the supra- and infrahyoid muscles. 3) Distension of the UES by superior-lateral traction of the stylopharyngeal, palatalopharyngeal and salpingopharyngeal muscles. 4) Further distension of the UES due to intrabolus pressure, assisted by the weight and volume of the bolus. 5) Passive collapse of the distended UES, followed by closure through contraction of the CPM as the bolus passes (Desuter, 2019).

In UES dysfunction, the compliance of the muscle block is altered, or the signalling is impaired. This can cause misdirection of the bolus into the laryngeal vestibule, leading to choking, or, if the bolus is not cleared by coughing, aspiration. Several conditions can affect UES and CPM function, including neurological, inflammatory, neoplastic, or iatrogenic issues (Allen, 2016). Aging may also weaken and reduce the size of the CPM, contributing to dysfunction (Nishikubo et al., 2015).

There is an anatomically weak area between the inferior pharyngeal constrictor and the CPM called Killian's triangle. This is the site where the most common pharyngeal diverticulum, Zenker's diverticulum (ZD), develops (Ferreira et al., 2008; Howell et al., 2023). Other potential areas of for pharyngo-oesophageal diverticula include the Killian-Jamieson, located anterolaterally, and Laimer-Hackerman's triangle, located dorsally, where lateral, Killian-Jamieson or Laimer's diverticulum, may form (Guo et al., 2023; Ekberg & Nylander, 1983; Rubesin & Levine, 2001) (Figure 2).

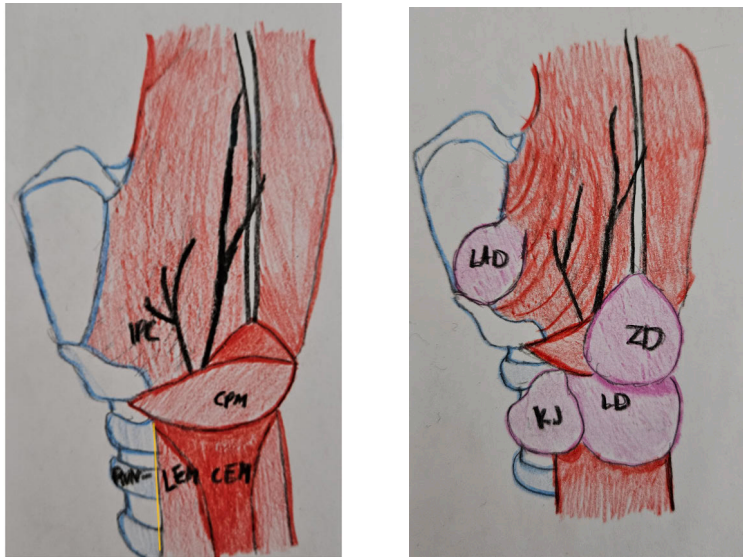


Figure 2. An illustration showing the anatomy of Zenker's diverticulum (ZD), Killian-Jamieson diverticulum (KJ), lateral diverticulum (LAD), and Laimer's diverticulum (LD). Abbreviations: CEM refers to the circular oesophageal muscle, CPM to the cricopharyngeal muscle, IPC to the inferior pharyngeal constrictor, LEM to the longitudinal oesophageal muscle, and RLN to the recurrent laryngeal nerve. Illustration: Kuuskoski Valma (2024).

Conditions like achalasia, cricopharyngeal spasm, cricopharyngeal dyscoordination, fibrosis, or congenital weakness have been implicated as the main causes of pharyngeal diverticula formation. Gastroesophageal reflux disease (GERD) has also been suggested to contribute significantly to ZD formation (Sasaki et al., 2003). However, there is still no consensus on the exact aetiology (Cook et al., 1992; Ferreira et al., 2008; Sutherland, 1962; Veenker et al., 2003). Iatrogenic, traction-type diverticula in hypopharyngeal area have also been observed, typically following cervical spine surgery (Dhar et al., 2020).

ZD is typically diagnosed in older adults. A recent population-based study from Finland reports an incidence of 2.9 per 100 000, with a mean onset age of 72 years. Incidence was higher in men than in women (3.7 vs. 2.3 per 100 000 person-years) (Uoti et al., 2022).

Symptoms of pharyngeal pouches include complaints of dysphagia, regurgitation of undigested food, halitosis, and voice issues. An audible gurgling sound, known as Boyce's sign or cervical borborygmus, during or after eating is also typical for pharyngeal diverticula (Sharma et al., 2019).

The retrograde function of UES refers to the relaxation of the segment, allowing air to pass upwards during belching or burping. In retrograde cricopharyngeus dysfunction (R-CPD), this process fails, leading to symptoms such as the inability to

burp, bloating, discomfort, gurgling sounds, reflux-like symptoms, and flatulence. This condition can be effectively treated with botulinum toxin injections into the CPM (Bastian & Smithson, 2019).

2.2.2.5 Oesophageal dysphagia

Oesophageal dysphagia can result from mechanical or motility disturbances. Mechanical (obstructive) causes may include inflammation, tumours (such as cervical or thoracic osteophytes, oesophageal cancer, enlarged goiter, mediastinal neoplasia, or aortic enlargement), oesophageal rings and webs and occasionally swallowed foreign bodies or the ingestion of a corrosive substance (Kruger, 2014; Postlethwait, 1983).

The most common cause for oesophageal dysphagia is GERD, which can lead to esophagitis, and when prolonged, peptic strictures, oesophageal rings (Schatzki rings), motility disorders, and intestinal metaplasia (Barret's oesophagus) (Kellerman & Kintanar, 2017; Tobin, 1998; Pandolfino & Roman, 2011). Antireflux surgery can also cause dysphagia (Wills & Hunt, 2001). Another relatively common cause of oesophageal inflammation leading to dysphagia is eosinophilic esophagitis (EoE), the prevalence of which has increased over recent decades (Lehman & Lam, 2021). EoE is an antigen-driven, Th2-mediated disorder that affects both children and adults, often associated with a history of asthma, atopy, or food allergies. In EoE, chronic eosinophil-dominated inflammation leads to oesophageal dysfunction, presenting with symptoms such as heartburn, regurgitation, vomiting, difficulty swallowing, food impactions, or chest or abdominal pain. Diagnosis is based on oesophageal biopsies showing eosinophilia. Endoscopic features may include linear furrows, mucosal rings, oesophageal narrowing, white plaques or exudates, strictures, or, in many cases, a normal-appearing oesophagus (Gonsalves & Aceves, 2020). Additionally, fungal or herpetic infections can also lead to dysphagia, especially in immunocompromised patients (Wilcox & Karowe, 1994).

After esophagitis, oesophageal motility disorders are the second most common cause of oesophageal dysphagia. According to Chicago Classification version 4.0 of oesophageal motility disorders, the diagnosis is based on high-resolution manometry (Yadlapati et al., 2021). Disorders of oesophagogastric junction outflow include achalasia (Type I, II, and III), and oesophagogastric junction outflow obstruction. Disorders of peristalsis include absent contractility, distal oesophageal spasm, hypercontractile oesophagus, and ineffective oesophageal motility (Patel et al., 2022; Yadlapati et al., 2021). Secondary motility disorders are caused by systemic diseases, such as scleroderma (Kadakuntla et al., 2021). In achalasia, the LES fails to relax adequately, and oesophageal peristalsis is reduced or absent, leading to functional obstruction, food stasis, and oesophageal dilatation (Vaezi et al., 2020).

Symptoms of oesophageal dysphagia include difficulty swallowing solids (and in some cases, liquids), a sensation of food sticking in the chest or throat, regurgitation, chest pain or discomfort after swallowing, heartburn or acid reflux, and weight loss due to reduced nutritional intake. Dysphagia affecting both solids and liquids is more indicative of motility disorders, while difficulty swallowing solids is more likely due to mechanical obstruction (Patel et al., 2022).

2.2.2.6 Functional dysphagia

Functional dysphagia refers to difficulty swallowing that occurs without any structural or organic abnormalities or a clear underlying physical cause in the digestive tract. In some dysphagia literature, the term may also describe disturbances in swallowing function observed during dysphagia evaluations, often linked to motor or sensory deficits (Massey & Shaker, 2006). However, in this thesis, functional dysphagia specifically refers to dysphagia with no known somatic aetiology.

Functional or persistent somatic symptoms are common, accounting for approximately one-third of healthcare consultations, in both primary care and specialised healthcare (Haller et al., 2015; Nimnuan et al., 2001). Functional or persistent somatic symptoms represent an umbrella category encompassing a range of conditions characterized by persistent and distressing physical symptoms that lead to impairment or disability (Burton et al., 2020). The term ‘unexplained’ or ‘non-organic’ should no longer be used (Marks & Hunter, 2015). On the front cover of *The Lancet* from June 15-21, 2024, there was a quote from Silje Endersen Reme: “Scientific developments since 2015 challenge the accuracy of the term medically unexplained symptoms, suggesting that these symptoms are both explainable and treatable” (Reme, 2024). This statement nicely summarizes the current understanding of these symptoms as expressions of the interconnected functioning and dysfunction of the body and brain, arising from complex interactions between various biological and psychosocial factors (Burton et al., 2020). The diagnosis of functional symptoms should focus on the symptoms themselves rather than being contingent upon identifying specific biological or psychosocial causes (Burton et al., 2020).

Functional dysphagia is a diagnosis of exclusion, requiring a comprehensive history, clinical examination, and instrumental evaluations to rule out identifiable organic or neurological causes (Bajens et al., 2013). Table 1 displays key characteristics, symptoms and findings of functional dysphagia.

Table 1. Key characteristics, symptoms and findings of functional dysphagia.

CHARACTERISTICS	SYMPTOMS	FINDINGS
Absence of structural or motility disorders	Feeling of food trapped in the throat or chest	Inappropriate chewing or bolus rolling in the mouth
Absence of profound psychological factors	Difficulty or fear of starting a swallow	Difficulty initiating swallowing
Absence of neuromuscular factors	Discomfort when eating or drinking	Absence of oropharyngeal findings
Inconsistent symptoms	Often 'illogical' diet (e.g. able to eat nuts but unable to eat rice), comfort foods	

Globus symptom is sometimes associated with functional dysphagia as both conditions can be influenced by stress, muscle tension, and anxiety. However, in globus, swallowing is typically unaffected or may even provide relief, whereas in functional dysphagia, swallowing is uncomfortable or difficult. Additionally, functional dysphagia may present with findings during swallowing evaluations, such as piecemeal deglutition or food pocketing in the mouth, while swallowing remains normal in globus (Baijens et al., 2013; Järvenpää et al., 2018). The key differences between functional dysphagia and globus are summarized in Table 2.

Table 2. Key differences between globus symptom and functional dysphagia.

	GLOBUS SYMPTOM	FUNCTIONAL DYSPHAGIA
PRIMARY SENSATION	Lump, tightness or discomfort in the throat	Difficulty swallowing
IMPACT ON SWALLOWING	Swallowing is unaffected and often provide relief	Swallowing is uncomfortable, difficulty initiating swallowing
PATHOPHYSIOLOGY	Often linked to throat muscle tightness, stress, or reflux	Related to brain stress mechanisms or hypersensitivity
DIAGNOSIS	Swallowing is normal	Some minor findings may be found

2.3 Evaluation of swallowing

2.3.1 Patient history and physical examination

Sir William Osler (1849-1919), one of the greatest physicians of all time, supposedly said: “Listen to the patient. He is telling you the diagnosis.” It is estimated that a thorough patient history allows the physician to determine 80 to 85 percent of the underlying causes of dysphagia (Spieker, 2000). By asking detailed questions about the onset, duration, and severity of the condition, along with related symptoms or potential precipitating factors, the physician can refine the differential diagnoses, potentially identifying a specific cause or pinpointing an anatomical or pathophysiological issue. While it is important to take the referrer’s specific concerns into account, it is even more crucial to focus on the patient’s own worries and complaints, which may differ from what was noted in the referral. Patient-reported outcome measures (PROMs), such as the EAT-10, may be helpful in this context.

The past medical history should cover at least cardiac, pulmonary, gastrointestinal, neurological, ear, nose, and throat (ENT) conditions, as well as any possible surgeries, psychological, and cognitive issues. Assessing oral hygiene and dental health is crucial when evaluating dysphagia and the risk of aspiration (Langmore et al., 1998; Loeb et al., 2003). It is also essential to review a list of current medications, as some may lead to xerostomia, drowsiness, or other symptoms that can affect swallowing (Ebadi et al., 1990; Miarons Font & Rofes Salsench, 2017). Social history and living arrangements, including a patient's level of independence and access to support, can influence both the diagnostic process and rehabilitation outcomes. Additionally, assessing nutrition, dietary habits, and any changes in eating patterns, along with potential compensatory strategies, is essential for evaluation. Any voice problems or changes in vocal quality, such as hoarseness, breathiness, or a wet-gurgling voice after eating or drinking, should also be noted.

The examination of a patient with oropharyngeal dysphagia symptoms includes assessing otorhinolaryngologic status through oral motor evaluation, laryngoscopy, neck palpation, and cranial nerve function testing related to swallowing. Immediate instrumental examinations are necessary if alarming signs such as weight loss, painful swallowing, severe food sticking in the throat or oesophagus, worsening hoarseness, or increasing symptom severity, are present. In the absence of these red flags, further tests may not always be required, particularly to rule out malignancy (Nevalainen et al., 2016). Symptoms that are inconsistent, illogical, or involve difficulties with the initiation of swallowing or piecemeal swallowing without any oral motor deficits may indicate functional dysphagia (Baijens et al., 2013; Verdonschot et al., 2019). It is also crucial to distinguish dysphagia from globus

sensation, which is the feeling of a lump in the throat that often improves when swallowing food or liquids (Galmiche et al., 2006).

2.3.1.1 Localisation of dysphagia symptom

Oropharyngeal dysphagia symptoms are typically evaluated by an otorhinolaryngologist. Oral problems, on the other hand, may lead to referrals to a dentist, while suspected neurological causes of dysphagia warrant consultation with a neurologist. In contrast, chest pain and the sensation of food sticking in the chest are indicative of oesophageal dysphagia, often leading to referrals to a gastroenterologist or gastrointestinal surgeon. Problems involving the UES or upper oesophagus are generally managed by an otorhinolaryngologist, while lower oesophageal issues are addressed by a gastroenterologist or gastrointestinal surgeon. Since ENT examinations and FEES only visualize the pharyngeal area, VFS or other oesophageal evaluations are necessary when UES or oesophageal problems are suspected.

However, this division is not always straightforward, as swallowing is a dynamic process, with effective pharyngeal swallows enhancing oesophageal peristalsis. Additionally, disturbances in oesophageal function can manifest as oropharyngeal symptoms, meaning that abnormalities may occur in both phases (Edwards, 1974; Gullung et al., 2012; Jones et al., 1985). The complaint of ‘food sticking in the throat’ has been reported in 21% to as high as 71% of cases, where the underlying issue is localized solely to the oesophagus, even when the pharyngeal phase appears normal (Edwards, 1974; Madhavan et al., 2015; Smith et al., 1998; Wilcox et al., 1995). Conversely, the complaint of ‘food sticking in the oesophagus’ is more reliable, with 80% of patients accurately localizing their symptom to the lower oesophagus (Roeder et al., 2004). Thus, the symptom of ‘food sticking’ is more likely to indicate an oesophageal problem, even when patients localize the sensation to the pharynx.

2.3.2 Patient-reported outcome measures

Patient-reported outcome measures (PROMs) can enhance communication between patients and healthcare professionals, improve patient engagement, and are useful in follow-up (Porter et al., 2016). However, the use of PROMs requires patients to have adequate cognitive and communication abilities. In the field of dysphagia, PROMs are widely used to assess the impact of dysphagia on HRQoL and to evaluate the effectiveness of treatments and interventions. Over 30 dysphagia-related PROMs are available (Patel et al., 2017). However, concerns have been raised about the poor psychometric properties or lack of comprehensive psychometric evaluation of many existing dysphagia measures (Cordier et al., 2017, 2018; Speyer et al., 2022).

Furthermore, many of these questionnaires are highly detailed, lengthy, and time-consuming, making them impractical for routine clinical use.

2.3.2.1 The Eating Assessment Tool, EAT-10

In 2008, Belafsky and colleagues published the Eating Assessment Tool (EAT-10) to provide a quick and simple dysphagia assessment tool. It was designed for use during each patient visit to evaluate the severity of dysphagia symptoms, the impact on quality of life, and treatment effectiveness (Belafsky et al., 2008). The EAT-10 consists of 10 items focusing on key aspects of dysphagia, with each item scored on a 5-point scale, ranging from no difficulty (0 points) to severe difficulty (4 points). The total score is the sum of all 10 items, with a score greater than 2 indicating a potential for dysphagia. This tool is easy to administer and takes less than two minutes to complete (Belafsky et al., 2008; Demir et al., 2016; Giraldo-Cadavid et al., 2016; Nogueira et al., 2015; Schindler et al., 2013). It has been proven to be a reliable clinical instrument, with strong internal consistency and test-retest reliability (Belafsky et al., 2008). Numerous translated and validated versions have been published (e.g. Abu-Ghanem et al., 2016; Burgos et al., 2012; Chung 2019; Demir et al., 2016; Frajkova et al., 2022; Lechien, Cavelier, et al., 2019; Möller et al., 2016; Nogueira et al., 2015; Printza et al., 2018; Schindler et al., 2013).

A relatively recent meta-analysis demonstrated that the EAT-10 is an effective tool for detecting dysphagia (Zhang et al., 2022). Additionally, some studies have suggested using the EAT-10 as a screening method to predict the risk of aspiration (Arslan et al., 2017; Cheney et al., 2014; Schlickewei et al., 2021), though there are also contradictory findings (Kendall, 2016). Currently, the EAT-10 is distributed by Nestlé Nutrition Institute (© Société des Produits Nestlé SA 2009).

2.3.2.2 Swallowing Quality of Life Questionnaire, SWAL-QOL

SWAL-QOL, published in 2002, consists of 44 items, organized into a symptom-frequency scale (symptoms, 14 items) and ten additional subscales: burden, desire to eat, eating duration, food choices, communication, fear of eating, mental health, social interactions, fatigue, and sleep. Additionally, SWAL-QOL assesses dietary intake through three specific items, while a final question captures the patient's overall perception of their general health (McHorney et al., 2002). Despite its popularity and the availability of many translated and validated versions, SWAL-QOL has faced criticism for including abstract questions about health indicators such as sleep patterns. Moreover, the complex wording of the questionnaire and the numerous response options per statement may be challenging for some patients to understand (Silbergleit et al., 2011).

2.3.2.3 Dysphagia Handicap Index, DHI

DHI was developed in 2011 with the goal of creating a simpler questionnaire than the SWAL-QOL to assess the handicapping effects of dysphagia on emotional, functional, and physical aspects of a patient's life (Silbergleit et al., 2011). The DHI consists of 25 statements divided into three domains: physical aspects of dysphagia (9 items), addressing the patient's perception of physical discomfort; functional aspects (9 items), assessing the impact of dysphagia on daily activities; and emotional aspects (7 items), exploring the emotional response to dysphagia. For each statement, patients indicate whether it applies to them always, sometimes, or never, with a recommended scoring of 4, 2, and 0, respectively. The total DHI score ranges from 0 to 100, with higher scores indicating a poorer quality of life. Additionally, after completing the questionnaire, patients rate their perceived swallowing difficulty on a scale of 1 (normal) to 7 (severe problem). Normative values have been published in recent meta-analysis (Sobol et al., 2021).

2.3.2.4 Other

There are also many disease-specific instruments, such as the MD Anderson Dysphagia Inventory (MDADI), which was designed to evaluate the quality of life in head and neck cancer (HNC) patients (Chen et al., 2001). Other examples of disease-specific dysphagia-related PROMs include the Measure of Achalasia Severity (MADS) for assessing patients with achalasia, the Dysphagia in Multiple Sclerosis (DYMUS) for patients with multiple sclerosis, and the Swallowing Outcome After Laryngectomy (SOAL) for patients after laryngectomy (Alali et al., 2018; Govender et al., 2012; Urbach et al., 2005).

2.3.3 Screening tests

The purpose of screening is to identify individuals at risk of dysphagia and its complications, who may therefore require further evaluation. Screening is particularly beneficial in populations with an increased risk of dysphagia, such as patients with neurological conditions, head and neck cancer, or critically ill patients in intensive care units (Speyer et al., 2022; Zuercher et al., 2019). Frail elderly individuals are also at increased risk for swallowing problems (van der Maarel-Wierink et al., 2014). The primary goal of screening dysphagia is to prevent complications, such as aspiration and malnutrition, by planning interventions like non-oral feeding in advance and ensuring proper oral health care (Speyer et al., 2022; Zuercher et al., 2019).

An optimal screening test should be brief, easy to perform, and reliable in detecting individuals who require further evaluation. Screening focuses on

identifying signs of swallowing difficulties, such as coughing, choking, voice changes, or abnormal swallowing behaviour. Some tests are more detailed and require additional time and effort to complete. For example, tests like the Volume-Viscosity Swallow Test (V-VST) not only screen for dysphagia but also provide information to guide dietary recommendations, making them more suitable to classify as non-instrumental assessment tools.

A wide range of screening tests and non-instrumental assessments are available. In 2021, the European Society for Swallowing Disorders (ESSD) published a White Paper that provides an overview of the current state of screening, including available measures and guidance on how to select appropriate screening tools and assessments (Speyer et al., 2022).

2.3.3.1 Water swallow tests

The principle of the WST is simple: the patient drinks water and the fluency of their drinking is observed. There are many variations of the test. The first, and likely the most used, is the 3-ounce water test, which was developed at the Burke Rehabilitation Center in Boston. In this test, the patient is asked to drink 3 ounces (approximately 89 ml) of water. Drinking continuity, as well as any coughing, choking during or after drinking, or a post-swallow wet-hoarse voice, are scored as either normal or abnormal (DePippo, 1993). Later, it was incorporated into the Burke Dysphagia Screening Test (BDST), where seven categories are observed: 1. Bilateral stroke, 2. Brainstem Stroke, 3. History of pneumonia in the acute stroke phase, 4. Coughing associated with feeding or during the 3-ounce water swallow test, 5. Failure to consume half of meals, 6. Prolonged time required for feeding, and 7. A non-oral feeding program in progress. The presence of one or more of these features is considered a failure of the test (DePippo et al., 1994). The 3-ounce test is also part of the Yale Swallow Protocol, which includes a brief cognitive screening and an oral mechanism examination prior to WST (Suiter et al., 2014).

In addition to the qualitative parameters introduced by DePippo et al., quantitative parameters can also be assessed. In “the Timed test” by Nathadwarawala et al., the patient is instructed to drink 150 ml of water as quickly as possible but to stop if difficulty arises. Along with observing for coughing during or after drinking, the number of swallows is counted, time is recorded, any residual volume is measured, and further calculations are made for swallowing speed (ml/s) and average drinking bolus size (ml) (Nathadwarawala et al., 1992). The specific parameters used in studies can vary (Hinds & Wiles, 1998; Wu et al., 2004).

There is also variability in the amount of water used in WSTs, ranging from 89 to 150 ml consumed in consecutive sips (DePippo et al., 1994; Kidd et al., 1993; Nathadwarawala et al., 1992; Suiter & Leder, 2008). Variations also include single

sips of small (1–5 ml) or large volumes (6–20 ml) and progressive volume challenges. These tests have been evaluated in meta-analysis (Brodsky et al., 2016), which concluded that consecutive sips with large volumes, in the absence of choking or voice changes, effectively ruled out the risk of aspiration. Small volumes with single sips effectively detected aspiration when clinical signs (coughing, choking, wet-hoarse voice) were present. However, swallowing speed was not analysed in this meta-analysis. In the metric system, the 100 ml water swallow test is likely the most useful and quick to perform.

2.3.3.2 Volume-viscosity swallow test

The Volume-viscosity swallow test (V-VST) was developed to assess both the safety and efficacy of swallowing (Clavé et al., 2008). The test evaluates swallowing using different consistencies and increasing bolus volumes: 5 ml, 10 ml, and 20 ml. It begins with nectar viscosity, and if no clinical signs of impaired efficacy (such as poor oral closure, or oral and pharyngeal residue) or impaired safety (e.g., wet-hoarse voice, choking or a drop in oxygen saturation greater than 3%) are observed, the test proceeds to thinner liquid and finally pudding-like consistencies with increasing volumes. In a systematic review, the V-VST demonstrated a diagnostic sensitivity of 93.17%, and a specificity of 81.39% for detecting oropharyngeal dysphagia (Riera et al., 2021). However, completing the test with all volumes and viscosities requires some time and effort.

2.3.3.3 Other

Cervical auscultation and pulse oximetry have been part of clinical swallow evaluations, particularly for assessing swallow safety when instrumental examinations are unavailable. Pulse oximetry is used to detect drops in oxygen saturation, which may indicate aspiration during swallowing. However, meta-analyses and systematic reviews have not confirmed the effectiveness of pulse oximetry in reliably detecting aspiration (Britton et al., 2018). Similarly, a 2016 systematic review found inconsistent evidence regarding the validity and reliability of cervical auscultation, and it did not recommend using the method independently for dysphagia detection (Lagarde et al., 2016).

Nevertheless, more recent studies have demonstrated that cervical auscultation, specifically evaluating swallow-respiratory sound sequences, shows strong accuracy and moderate to good reliability in assessing swallow safety when compared to FEES (Jaghbeer et al., 2023). Tongue strength and endurance measurement, commonly performed using the Iowa Oral Performance Instrument (IOPI), has also

been utilized in swallowing assessments, particularly for individuals with Parkinson's disease (Adams et al., 2013; Pitts et al., 2022).

2.3.3.4 Non-instrumental bedside assessment

While screening tools serve as a first-line method to detect dysphagia risk, non-instrumental swallowing assessments are more detailed clinical evaluations of swallowing function conducted without specialized tools or imaging equipment. These assessments rely on observation, patient history, and physical examination to identify potential swallowing impairments.

Traditional bedside assessments include reviewing the medical chart, conducting an oral motor examination, and observing the patient during eating or drinking. Such assessments are typically performed by nurses, Speech and Language Pathologists (SLPs), or other healthcare professionals (Boaden et al., 2021). The bedside swallowing evaluation (BSE) usually includes a swallowing test, such as the WST or the V-VST. However, the specific tools and methods used can vary between hospitals and healthcare professionals.

A typical BSE evaluates several factors: lip movement and oral closure, tongue movement and strength, volitional cough strength, dentition and mastication, voice quality, and the need for feeding assistance. If possible, the patient is seated upright. The test then proceeds with five standard consistencies: 1) 1 tsp ice chips 2) 1 tsp nectar-thick liquid 3) 1 tsp pureed solid (e.g., fruit puree or pudding) 4) 5 ml thin liquids (e.g., water or milk), and 5) solids (e.g., a cracker or cookie). Five signs of aspiration are monitored within 10 seconds: coughing, throat clearing, changes in voice quality, wet breath sounds, or stridor. Pulse oximetry is also monitored, with a drop of <3% noted during the BSE. If the patient passes the consistency trials, the test may continue with the WST (Lynch et al., 2017).

There are many variations of bedside screening tests. The Toronto Bedside Swallowing Screening Test (TOR-BSST©) has two steps: the first screens for abnormalities in tongue movement or voice quality, and the second involves administering ten consecutive teaspoons of water (Martino et al., 2009). The Gugging Swallowing Screen (GUSS) assesses awareness, cough strength, saliva management, and trials of liquid and solids, with scoring-based recommendations for diet and oral intake (Trapl et al., 2007). GUSS has also incorporated the International Dysphagia Diet Standardisation Initiative (IDDSI) framework for standardizing different viscosities (Cichero et al., 2017; <https://www.iddsi.org/>).

In addition to WSTs, the oral phase and solid bolus ingestion are assessed with the The Test of Masticating and Swallowing Solids (TOMASS), where the patient's ability to eat a cracker is observed (Huckabee et al., 2018).

The Mann Assessment of Swallowing Ability (MASA) includes 24 clinical parameters designed to identify swallowing disorders (Mann, 2002). MASA, like most other screening tests, is intended for use by nurses, paramedics, SLPs or other healthcare professionals after special training. A modified version of MASA, the MMASA, is tailored for physicians treating acute stroke patients (Antonios et al., 2010).

Most swallowing screening tools are freely available, though the use of TOR-BSST© requires attendance at online training.

2.3.4 Instrumental examinations

2.3.4.1 Flexible endoscopic evaluation of swallowing, FEES

In the endoscopic evaluation of swallowing, the patient swallows various food consistencies (e.g. liquid, puree, solid) while the swallowing process is viewed via a flexible endoscope inserted through the nostril (Figure 3, 4, 5). This procedure is usually performed collaboratively by a physician and a SLP and can include patient instruction using the video footage, making it an important tool for both diagnosing and treating patients with dysphagia.



Figure 3. Flexible endoscopic evaluation of swallowing. The individuals in the image have given permission for the publication of the photograph. Image: Kuuskoski J.



Figure 4. Flexible endoscopic evaluation of swallowing is performed with a thin videoendoscope and usual consistencies are liquid, nectar, puree and solid. Image: Kuuskoski J.

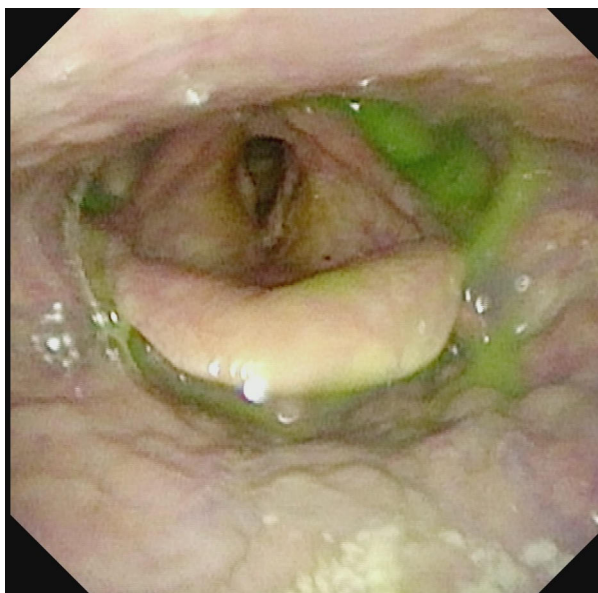


Figure 5. Pharyngeal residues and penetration were seen on Flexible endoscopic evaluation of swallowing in a 74-year-old male with a history of vocal cord carcinoma treated with cordectomy and irradiation 30 years ago, and a cerebral infarction 10 years ago. Image: Kuuskoski J.

The term “FEES” was initially introduced by Langmore et. al. as “Fiberoptic Endoscopic Examination of Swallowing Safety” (FEES) (Langmore et al., 1988). Nowadays, as videoendoscopes have superseded fiberoscopes, the examination is referred as “Flexible Endoscopic Evaluation of Swallowing”. The term “Videoendoscopic Evaluation of Dysphagia” (VEED) has also been published (Bastian, 1991).

FEES with sensory testing (FEESST) was introduced by Aviv et al., wherein the sensory function of the superior laryngeal nerve is tested using air pulse stimulation to the pyriform fossa and aryepiglottic folds (Aviv et al., 1998). Narrow band imaging (NBI) and food colouring can further enhance diagnostics in FEES (Fleischer et al., 2017). Recently, interest has shifted toward detecting different swallowing phenotypes to facilitate differential diagnostics. Desuter described “Swallow Video Endoscopy” (SVE), where the evaluation of swallowing is combined with an analysis of different swallowing scenarios, or phenotypes, to guide further referrals and treatment (Desuter, 2019). The swallowing phenotype can also provide valuable insight into the underlying diagnosis of neurogenic dysphagia (Warnecke et al., 2021).

FEES provides an excellent platform for biofeedback and evaluating therapeutic interventions, thus, becoming the gold standard examination for evaluating oropharyngeal dysphagia alongside VFS. FEES is often regarded as superior to VFS for assessing pharyngeal residue, laryngeal penetration, aspiration, the effectiveness of the cough reflex, and velopharyngeal closure (Langmore et al., 1991; Wu et al., 1997). However, FEES does not reveal structural or functional abnormalities of the UES or oesophagus.

Several rating systems have been employed in FEES. The Yale Pharyngeal Residue Severity Rating Scale is beneficial for residue rating (Neubauer et al., 2015). The Penetration-Aspiration Scale (PAS) is commonly used to rate the depth of penetration or aspiration and the patient’s response (Rosenbek et al., 1996). The Dynamic Imaging Grade of Swallowing Toxicity (DIGEST) was originally developed to quantify VFS imaging findings and the severity of pharyngeal dysphagia in HNC patients, but it has also been validated for FEES (DIGEST-FEES) (Hutcheson et al., 2017; Simon et al., 2023; Starmer et al., 2021). DIGEST-FEES has also been validated for assessing pharyngeal dysphagia severity in patients with Parkinson’s disease (Labeit et al., 2024).

2.3.4.2 Videofluoroscopy

Videofluoroscopy (VFS) and videofluorography are imaging techniques that use X-rays to capture real-time dynamic motion within the body. In swallowing studies, this examination is often referred to as a modified barium swallow, although other contrast agents, such as iohexol, can also be used. Videofluorography typically

focuses on recording images for later review, while videofluoroscopy emphasizes live observation of movement. However, the terms are often used interchangeably. Radiographic techniques such cineradiography (2–8 X-rays per second), provide higher contrast and detailed anatomical views but require higher radiation doses. Fluoroscopic techniques, typically operating at 15–30 pulses per second, effectively capture motion. Advances in digital imaging have reduced radiation exposure by 10 to 100 times, while still maintaining clear anatomical and mucosal detail (Delahaut & Van der Vorst, 2019). During VFS, the patient swallows liquid and solid mixtures containing contrast agents, and the swallowing process is recorded under fluoroscopy. Since the 1970s, VFS has been the gold standard for evaluating dysphagia (Levine & Rubesin, 2017). Figure 6 presents the VFS setting.



Figure 6. Videofluoroscopy setting in Turku University Hospital. Image: Kuuskoski J.



Figure 7. Findings in videofluoroscopy can be oral, pharyngeal or oesophageal. Image: Kuuskoski J.

VFS provides clear visualization of both the oropharyngeal and oesophageal phases of swallowing, like shown in Figure 7. In contrast to FEES, VFS effectively diagnoses upper oesophageal segment function and oesophageal structural abnormalities, such as Zenker's diverticulum and strictures. Additionally, it allows for a comprehensive assessment of the entire swallowing process and can detect potential aspiration. VFS can also reveal peristaltic abnormalities in oesophagus. Findings, such as a lack of peristalsis, a dilated oesophagus with 'bird beaking' above the LES, and poor oesophageal emptying are indicative of achalasia (Vaezi et al., 2020).

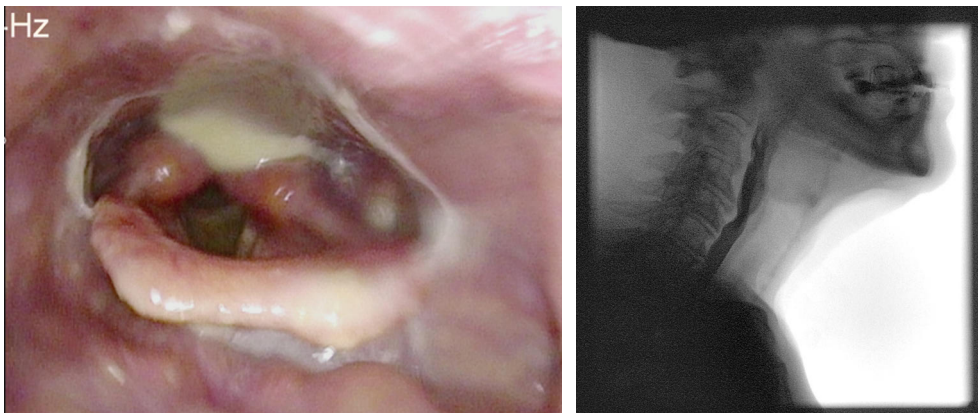


Figure 8. Flexible endoscopic evaluation and videofluoroscopy images of an 87-year-old male show pharyngeal residues due to an osteophyte observed during videofluoroscopy. The patient reports difficulty eating solid foods, a sensation of food sticking in the throat, and occasional coughing while swallowing. Image: Kuuskoski J.

FEES and VFS often complement each other (Figure 8). Although VFS is widely used to assess dysphagia, there is variability in the use of radiographic or fluoroscopic techniques, patient positioning, contrast agents, boluses and consistencies used, and imaging protocols. Furthermore, the interpretation and analysis of VFS results can vary. Several rating systems have been developed to standardize findings, including the Videofluoroscopic Dysphagia Scale, Modified Videofluoroscopic Dysphagia Scale, the Group for Learning Useful and Performant Swallowing (GLUPS), and Modified Barium Swallow Impairment Profile (MBSImp) (Chang et al., 2021; Kim et al., 2014; Lechien, Cavelier, et al., 2019; Martin-Harris et al., 2008; McCullough et al., 2001; Scott et al., 1998). Most of these focus on the oropharyngeal phase.

The inter-rater reliability of many of these subjective assessment methods has been found to be unsatisfactory, prompting the development of objective, measurement-based approaches for rating VFS findings (Chang et al., 2021; Chun

et al., 2011; McCullough et al., 2001; Scott et al., 1998). Among these, MBSImp has demonstrated good inter- and intra-rater reproducibility; however, it requires licensed, relatively costly training, which limits its accessibility (Martin-Harris et al., 2008). Dynamic Imaging Grade of Swallowing Toxicity (DIGEST) and its versions have gained popularity for rating dysphagia severity in HNC patients and have also been applied to other aetiologies, such as rating oesophageal atresia (Demir et al., 2024; Hutcheson et al., 2017, 2022).

Kendall and Leonard et al. have introduced temporal and spatial parameters for normal and abnormal swallowing. While these objective measures offer precision, they are time-consuming and have yet to gain widespread clinical adoption (Kendall, 2000; Leonard et al., 2000).

The Pharyngeal Constriction Ratio (PCR) was later introduced as a quantitative measure of pharyngeal strength using fluoroscopic studies (Leonard et al., 2011). PCR is calculated by comparing the pharyngeal area at the bolus hold position (PA_{hold}) to its area at maximal constriction (PA_{max}). Leonard et al. demonstrated a strong inverse correlation between PCR and peak pharyngeal pressure on manometry, supporting its validity as an indicator of pharyngeal strength.

2.3.4.3 Endoscopy

Reliable assessment of the mucous membranes of the lower throat requires a hypopharyngoscopy, a procedure performed under general anaesthesia using a rigid endoscope. Esophagogastroduodenoscopy (EGD), the most common method for examining the oesophagus, stomach, and duodenum, is typically performed with a flexible endoscope inserted through the mouth. Esophagoscopy can also be done with a rigid endoscope under general anaesthesia, allowing for optimal visualisation of the PES and enabling procedures such as dilatation, injections, myotomies, and foreign body removal. Transnasal esophagoscopy (TNE) can be performed in-office, permitting safe and well-tolerated visualisation of the entire pharynx and larynx before the oesophageal examination (Aviv et al., 2001; Belafsky et al., 2001; Postma, 2006; Shaker, 1994). The working channel in the scope allows for biopsies, and other procedures, such as injections or dilatation, are also possible (Wellenstein et al., 2017).

Endoscopy is recommended as the initial examination for patients with alarming symptoms like weight loss, painful swallowing, or food retention in the oesophagus, in order to rule out malignancy (Katz et al., 2013). Endoscopy is both a diagnostic tool and allows for various therapeutic procedures in the oesophagus, such as balloon or bougie dilation, oesophageal stent placement, radiofrequency ablation for Barrett's oesophagus, endoscopic mucosal resection, endoscopic submucosal dissection, and oesophageal variceal ligation (Gralnek et al., 2022; Shaheen et al., 2009; Egan et al., 2006; van den Berg et al., 2016). To accurately assess for

eosinophilic esophagitis, it is recommended to obtain multiple biopsies—typically 2 to 4 samples—from at least two distinct locations in the oesophagus, most commonly from the distal and proximal regions, or from areas with macroscopically abnormal mucosa (Dellon et al., 2013).

2.3.4.4 Manometry

Oesophageal manometry involves the insertion of a thin catheter through the nose into the oesophagus, where sensors measure pressure at multiple points. Since its development in the 1990s, oesophageal high-resolution manometry (HRM), which utilizes up to 36 sensors, has become the gold standard for assessing oesophageal motility patterns and is widely used in clinical practice (Kahrilas et al., 2015; Yadlapati, 2017). Recent advancements in HRM include the incorporation of provocative manoeuvres during testing, the addition of impedance monitoring, and its expanded use in investigating oesophageal pathophysiology, such as GERD. The Chicago Classification, with the most recent version being 4.0, provides a standardized approach to interpreting clinical HRM studies and is used to identify and categorize oesophageal motility disorders (Yadlapati et al., 2021). HRM is also valuable in treatment planning (Nicodème et al., 2014; Wang et al., 2016). Manometry, together with multichannel intraluminal impedance monitoring, plays a crucial role in diagnosing functional gastrointestinal disorders, including rumination syndrome and supragastric belching (Davidson et al., 2023; Kessing et al., 2014a, 2014b; Moshiree et al., 2023).

In recent years, high-resolution pharyngeal manometry (P-HRM), including impedance (P-HRM-I), has gained increasing popularity (Knigge et al., 2014; Omari et al., 2011, 2020, 2023). This catheter-based diagnostic technique evaluates pressure dynamics within the pharynx and UES during swallowing. P-HRM provides detailed insights into swallowing physiology and is particularly valuable for identifying abnormalities in the swallowing mechanism, including UES dysfunction. It can assist in planning targeted interventions such as UES dilatation, injections, or myotomy (Cock & Omari, 2017). Furthermore, it can detect signs of inefficient or unsafe bolus transport, offering predictive insights into the risk of aspiration (Bayona et al., 2022). P-HRM is especially effective for diagnosing and managing complex swallowing disorders, as it reveals pressure patterns that contribute to impaired swallowing mechanics (Omari et al., 2023).

2.3.4.5 Multichannel intraluminal impedance-pH monitoring

In multichannel intraluminal impedance-pH monitoring (MII-pH), also referred to as impedance-pH-metry or ambulatory 24-hour impedance monitoring, a catheter is

placed through the nose into the oesophagus to record changes in electrical resistance (impedance) within the oesophagus, alongside pH monitoring to determine acid levels. It identifies reflux of liquid, gas or mixed contents irrespective of their pH. It helps to differentiate acid reflux ($\text{pH} < 4$) from weakly acidic ($\text{pH} > 4$ but < 7) and non-acid ($\text{pH} > 7$) reflux. It can also track the movement of bolus through the oesophagus, evaluating oesophageal motility and clearance. By maintaining a symptom diary during the test, clinicians can evaluate the cause-and-effect relationship between symptoms and reflux events. MII-pH is considered the most precise and sensitive method for detecting all forms of gastroesophageal reflux, allowing for detailed characterization of reflux episodes, while traditional pH monitoring identifies changes only in pH (Villa & Vela, 2013). MII-pH is particularly beneficial for symptomatic patients with proven GERD, who experience persistent oesophageal symptoms despite proton pump inhibition therapy or other treatments (Yadlapati et al., 2022).

MII-pH is also useful in diagnosing LPR. However, the absence of well-defined diagnostic criteria for LPR complicates the interpretation of MII-pH results specific to this condition (Lechien, Akst, et al., 2019). Additionally, the oropharyngeal pH monitoring device (Restech; Respiratory Technology Corp, San Diego, California) is designed specifically for detecting LPR. However, studies have reported inconsistencies between acidic pharyngeal pH and acid reflux episodes in the oesophagus (Becker et al., 2012).

The 24-hour hypopharyngeal-oesophageal multichannel intraluminal impedance-pH monitoring (HEMII-pH) enhances traditional oesophageal impedance-pH monitoring by incorporating sensors in the hypopharynx to detect reflux reaching the upper airway. The European clinical practice guideline recently recognized HEMII-pH as the gold standard for diagnosing laryngopharyngeal reflux disease (LPRD), defining the condition as the presence of more than one pharyngeal reflux event (Lechien et al., 2024). Additionally, expert consensus has proposed an empirical therapeutic trial, including lifestyle modifications and post-meal alginates or antacids, as an alternative diagnostic approach for LPRD.

2.4 Treatment of dysphagia

2.4.1 Treatment of dysphagia according to aetiology

The treatment of dysphagia primarily focuses on addressing its underlying cause, with the ultimate goals being to enhance swallowing safety, ensure adequate nutrition and hydration, and improve the patient's quality of life. Management approaches are tailored to the aetiology and severity of symptoms and may encompass lifestyle modifications, therapeutic interventions, and medical or surgical

procedures. Specific measures include mucosal lubricating techniques and dietary adjustments, such as transitioning to soft or pureed foods. Speech and swallowing therapy often proves effective in strengthening muscles and enhancing swallowing coordination (Poertner & Coleman, 1998). Additionally, maintaining good oral health through proper dental care is essential component of dysphagia management (Pace & McCullough, 2010).

Medical or surgical options for oesophageal dysphagia might involve medications, botulinum toxin injections, oesophageal dilatation, or surgical procedures like cricopharyngeal myotomy or surgery for Zenker's diverticulum (Shama et al., 2008). Peroral endoscopic myotomy (POEM) is increasingly used in the treatment of achalasia and oesophageal diverticula (Kohn et al., 2021; Ren et al., 2024)

Other surgical options may involve surgery for velopharyngeal insufficiency, laryngochoyoid suspension, vocal cord medialization or augmentation for glottic insufficiency, hypopharyngeal reduction pharyngoplasty, surgery for sialorrhea, tracheotomy, or, in extreme cases, laryngotracheal separation or laryngectomy (Tedla & Carrau, 2019).

Education is also essential: providing information about normal swallowing, identifying the specific issues causing dysphagia, and validating the patient's concerns help foster understanding and cooperation. FEES offers valuable insights into swallowing mechanics and may even serve as a therapeutic tool (Thottam et al., 2015).

A thorough medication review is crucial, as certain drugs can impair swallowing function or cause mucosal dryness (Miarons Font & Rofes Salsench, 2017; Miarons et al., 2016). Several pharmacological agents, including levodopa, piperine, capsaicin, and angiotensin-converting-enzyme inhibitors, have shown potential to enhance swallowing function by increasing substance P levels and improving reflexes (Ebihara et al., 2005, 2006; Fonda et al., 1995; Nakayama et al., 1998; Rofes, Arreola, Martin, et al., 2014; Rofes et al., 2013). However, the effect appears to be short-lived and limited to acute administration. Medical treatment for oesophageal motility disorders often involves agents like anticholinergics, nitrates, or calcium channel antagonists, but clinical outcomes are generally modest. Calcium channel blockers, alone or with anticholinergics or nitrates, may be tried, particularly in mild achalasia (Storr & Allescher, 1999).

Proper nutritional management is critical, even when a formal dysphagia diagnosis has not been established. Nutritionists play a key role in creating suitable dietary plans, and non-oral feeding methods may be necessary in some cases. For acute situations, nasogastric tubes or parenteral nutrition may be used, while long-term solutions can include percutaneous endoscopic gastrostomy (PEG).

2.4.1.1 Treatment of functional dysphagia

Diagnosing functional dysphagia involves a comprehensive history, clinical examination, and instrumental evaluations, such as FEES or VFS, to exclude organic or neurological causes (Baijens et al., 2013). While research on functional dysphagia and its treatment is limited, effective management typically follows principles used for other functional symptoms, emphasizing early diagnosis to improve outcomes and avoiding unnecessary tests that could heighten patient anxiety (Deary et al., 2007).

Patients with medically unexplained symptoms (now referred to as functional or persistent somatic symptoms) highly value a personalized approach. This includes physicians considering individual circumstances, conducting thorough examinations, communicating effectively, and treating patients as equal partners in their care (Houwen et al., 2017). A study by Järvenpää (née Nevalainen) et al., found that nearly half of patients with nonspecific or functional dysphagia symptoms became asymptomatic or experienced symptom relief after a three-year follow-up without specific treatments, suggesting a benign course of the condition (Nevalainen et al., 2016).

Managing functional symptoms is often challenging due to perpetuating factors, which may be physiological (e.g., autonomic dysfunction, sleep disturbances, central nervous system hypersensitivity, and dysregulation of the hypothalamic-pituitary-adrenal axis), social (e.g., ambiguity in medical diagnoses), cognitive (e.g., exaggerated symptom interpretation, fixation on symptoms, discomfort with uncertainty), or behavioural (e.g., avoidance behaviours, extreme actions, poor sleep habits) (Hamilton et al., 1996). Treatment often focuses on modifying these factors, particularly cognitive and behavioural elements (Hamilton et al., 1996).

A 2014 Cochrane review highlighted the benefits of cognitive behavioural therapy (CBT) for functional or persistent somatic symptoms, although its efficacy was similar to enhanced care provided by the patient's physician (Dessel et al., 2014). Psychodynamic approaches and mentalization-based therapy have also shown promise (Luyten & Fonagy, 2020).

A strong patient-physician relationship and validation of the patient's experience are crucial for positive outcomes (Deary et al., 2007; Houwen et al., 2017; Husain & Chalder, 2021; Van der Feltz-Cornelis et al., 2004). Conversely, excessive investigations and referrals can worsen symptoms by reinforcing maladaptive illness behaviours and interpretations (Deary et al., 2007).

Treatment of functional dysphagia combines approaches such as dietary modifications, behavioural therapy, swallowing exercises, and addressing psychological factors like anxiety (Baijens et al., 2013; Massa et al., 2022; Verdonschot et al., 2019). A protocolized shaping intervention that combines

graduated food exposure with anxiety reduction strategies has shown promise in treating children and adolescents with phagophobia (Begotka et al., 2022).

Providing a clear, rational explanation to patients is essential (Burton et al., 2015, 2024). FEES can aid by offering insights into swallowing mechanics and serving as a biofeedback tool (Thottam et al., 2015).

A recent multicentre, randomised controlled trial by Burton et al. (2024) introduced a symptom-clinic intervention as an effective treatment for functional symptoms. The intervention consisted of four modules: recognition (listening to and affirming the patient and their symptom), explanation (developing a personalised understanding based on scientific insights), action (teaching and practicing symptom management techniques), and learning (reinforcing new skills and knowledge) (Burton et al., 2024). This approach may also benefit patients with dysphagia of known aetiology.

Finally, the dualism between ‘organic’ and ‘functional’ conditions should be avoided, as all patients benefit from validation and a personalized approach.

3 Aims

The purpose of this study was to improve dysphagia diagnostics and evaluate feasible screening methods to identify patients who would benefit from instrumental examinations, while avoiding unnecessary investigations.

The specific aims of the four studies were to:

1. Translate and validate the Finnish version of the Eating Assessment Tool (EAT-10), investigating its clinical relevance for Finnish-speaking patients (I).
2. Assess the feasibility of employing quick and simple screening tools, WST and EAT-10, to identify patients requiring VFS referral (II).
3. Compare the inter-rater reliability and clinical utility of the subjective normal-abnormal VFS rating score with an objective, measurement-based method (III).
4. Evaluate symptom severity, HRQoL, and disability in dysphagia patients, as well as the impact of a one-time FEES intervention combined with swallowing guidance, particularly in patients with functional dysphagia (IV).

4 Materials and Methods

4.1 Patients and controls

All patients and controls for Studies I–IV were prospectively recruited. They were adults (>18 years), native Finnish speakers, without significant psychiatric or cognitive disorders, and were able to independently complete the study questionnaires (with assistance allowed for writing). Study I was a multicentre study, involving five university hospitals (Helsinki, Turku, Kuopio, Tampere, Oulu) and two central hospitals (Central Ostrobothnia and Vaasa), while Studies II–IV were conducted at a single institute (Turku University Hospital). Table 3 presents the characteristics of the patients and controls in all the studies.

Table 3. Summary of patient and control characteristics in all studies.

	STUDY I controls	STUDY I FEES- patients	STUDY I operative patients	STUDY II	STUDY III	STUDY IV
NUMBER OF PATIENTS	180	117	19	150	77	60
MEDIAN AGE, YEARS (RANGE)	57.0 (18.3–82.1)	69.7 (19.5–90.4)	75.8 (56.4–87.1)	70.0 (19–92)	72.0 (19–92)	65.0 (18–89)
MALE FEMALE	37.8% 62.2%	47.0% 53.0%	42.1% 57.9%	41.5% 58.5%	44.2% 55.8%	30.0% 70.0%
MEDIAN BMI (RANGE)	25.2 (16–49.5)	24.6 (15.2–62.0)	25.2 (18.0–34.0)	26.4 (17.0–52.4)	26.0 (17.0–43.8)	27.5 (16.9–48.3)

4.1.1 Study I

4.1.1.1 Controls

Normative data were collected from 180 non-dysphagic controls with a median age of 57.0 years (range 18.3–82.1), 62.2% of whom were female. These individuals were otological and audiological outpatients from the Helsinki University Hospital, Department of Otorhinolaryngology – Head and neck Surgery. They had no history of dysphagia, dysphonia, severe xerostomia, reflux, or neurological diseases (except for migraines). Additionally, they had no history of head and neck cancer, upper gastrointestinal or respiratory malignancies, or surgeries in the upper aerodigestive tract. Those who underwent adenotomy and tonsillectomy more than a year ago and had an uneventful recovery were not excluded.

4.1.1.2 Patients

Study I included two groups of dysphagia patients: those who underwent FEES (FEES patients) due to suspected oropharyngeal dysphagia, and those who had endoscopic surgery for Zenker's diverticulum or a tight CPM (operative patients).

A total of 127 FEES patients were recruited between September 2018 and June 2020 from four university hospitals (Helsinki, Turku, Kuopio, Tampere) and two secondary care hospitals (Vaasa Central Hospital and Central Ostrobothnia Central Hospital) through their ENT or phoniatrics outpatient clinics. Nine patients (7.1%) were excluded from the analysis because their baseline EAT-10 scores could not be calculated, and one additional patient was excluded for being underage (17 years). The final analysis included 117 FEES patients, with a median age of 69.7 years (range 19.5–90.4), and 53.0% of them were female.

The operative patient group consisted of 22 individuals with dysphagia undergoing endoscopic surgery for Zenker's diverticulum, a tight CPM, or both. These patients were recruited from four university hospital ENT clinics (Helsinki, Kuopio, Oulu, and Turku) between September 2018 and October 2020. Of the 22 operative patients, 21 (95.5%) returned the follow-up questionnaire, with 19 fully completing it, including the symptom change question. Data from these 19 patients (median age 75.8 years, range 56.4–87.1, 57.9% female) were used for criterion validity analysis.

The surgeries included balloon dilatation in nine patients (one of whom also received a botulinum toxin injection), stapler-assisted surgery for Zenker's diverticulum in seven, CO₂ laser myotomy in two, and one case of cricopharyngeal dilatation with rigid hypopharyngoscopy combined with a botulinum toxin injection.

Patients frequently undergoing cricopharyngeal procedures, such as those with head and neck cancer sequelae, were excluded.

4.1.2 Study II, III

Data for Studies II and III were collected from patients referred for VFS from various medical disciplines and primary health care at Turku University Hospital over a one-year period (June 2021 to June 2022). Study II included 151 consecutive patients, of whom one patient refused to drink water, leaving 150 patients with complete EAT-10, WST, and VFS data. The median age was 70 years (range 19–92), and 58.5% were female.

The analysis for Study III was obtained from the last consecutive 77 patients of Study II, recruited between December 2021 and June 2022. The calibration ball included in the imaging protocol allowed for measurement-based ratings.

4.1.3 Study IV

We recruited 60 consecutive patients referred to the phoniatrics outpatient clinic at Turku University Hospital for dysphagia. These patients originated from primary care or other medical specialties and were recruited between October 2021 and September 2023, with delays due to the COVID-19 pandemic and work arrangement issues. The median age of participants was 65 years (range 18–89), with 70% being female.

4.2 Methods

4.2.1 Questionnaires

4.2.1.1 EAT-10 (I, II, IV)

The EAT-10 questionnaire is designed to assess various dimensions of dysphagia. It includes 10 items, each rated on a 5-point Likert scale, where 0 indicates no difficulty and 4 signifies severe difficulty. The total score is the sum of the ratings for all items, ranging from 0 to 40 (Belafsky et al., 2008).

In Study I, the EAT-10 was translated into Finnish following the forward-backward translation method described by Wild et al. (2005). A native Finnish-speaking professional translator first translated the EAT-10 from English to Finnish. A native English-speaking professional then performed a back translation. Two experienced laryngologists also independently translated the EAT-10. After

comparing the translations, no significant differences were found. The final Finnish version of EAT-10 was completed after discussion among laryngologists at the Helsinki University Hospital's Department of Otorhinolaryngology, with minor adjustments for clarity. A pilot test with 10 dysphagic patients (median age 55.2 years, range 18–79, 60% male) did not lead to any further changes.

In Study I, both controls and FEES-patients completed the Finnish version of the EAT-10. To assess test-retest reliability, participants were asked to complete the EAT-10 again after two weeks. The baseline EAT-10 scores were also compared with FEES findings to evaluate how symptoms correlated with the results (criterion validity). In the operative patient group, participants completed the EAT-10 questionnaire both before surgery and three months afterward. An additional question was included to assess perceived changes in symptoms following the operation. This question was used to determine if changes in EAT-10 scores aligned with the patient's subjective symptom changes (criterion validity) and was rated on a scale from 0 to 4: 0 = no symptoms, 1 = fewer symptoms, 2 = same symptoms, 3 = slightly more symptoms, and 4 = much more symptoms than before the operation.

In Study II participants completed the EAT-10 before imaging, along with the WST. The correlations between EAT-10 total scores and VFS findings were analysed to determine the potential of EAT-10 as a screening tool for VFS referral.

In Study IV, patients completed the EAT-10 to assess their subjective evaluation of dysphagia symptoms and severity both before the FEES and at a one-month follow-up. The follow-up questionnaire also included a question to gauge changes in symptoms over the past 30 days, with the same scale as described above.

4.2.1.2 15D Health-Related Quality of Life Instrument (IV)

The 15D is a comprehensive PROM used to assess HRQoL across 15 dimensions: mobility, vision, hearing, breathing, sleeping, eating, speech, excretion, usual activities, mental function, discomfort and symptoms, depression, distress, vitality, and sexual activity. Each dimension is rated on a 5-point Likert scale, where 1 represents the best possible condition and 5 represents the worst. The overall HRQoL is quantified by a single index score (the 15D score), which ranges from 0 to 1, where 1 indicates full health and 0 indicates death (Sintonen, 2001, Appendix 2). Dimension-level values are derived from the questionnaire using population-based preference weights, reflecting levels from no problems (=1) to death (=0). Mean dimension-level values are used to create 15D profiles for groups. A minimal clinically important difference in the 15D score has been reported as 0.015 (Alanne et al., 2015). Normative values, adjusted for age and gender, are based on the Finnish National Health Survey 2011 (Koskinen et al., 2012).

In Study IV, patients completed the 15D questionnaire just before their outpatient visit and again after a one-month follow-up to evaluate their HRQoL.

4.2.1.3 WHODAS 2.0 (IV)

The WHODAS 2.0 is a standardised tool developed by WHO to assess health and disability (Üstün, 2010). It evaluates functioning across six domains of life: cognition (domain 1), mobility (domain 2), self-care (domain 3), social interactions (domain 4), life activities (domain 5.1 for household activities, and domain 5.2. for work and study), and participation in society (domain 6). WHODAS 2.0 is available in three versions: a 36-item version, a 12-item version, and a combined 12+24-item version, with the 36-item version providing the most detailed assessment.

Each item is rated on a 5-point Likert scale, ranging from 0 ("none") to 4 ("extreme"). Scores are summed for each domain and for the total. There are two scoring methods: the simple scoring method, which involves straightforward summation, and the complex method, based on item-response theory, which involves coding and weighting each item. In the complex method, domain scores are converted to a 0–100 scale, where 0 indicates no disability and 100 indicates complete disability (Üstün, 2010).

We used the Finnish version of the self-administered 36-item WHODAS 2.0 (Paltamaa, 2014). The simple scoring method was applied to compare results between the initial visit and a one-month follow-up, while complex scoring was used to compare patient data with normative values from the Swedish population, as Finnish population norms for WHODAS 2.0 are not available (Norén et al., 2023). Given the geographical and cultural similarities between Finland and Sweden, the Swedish norms are considered comparable.

In Study IV, patients completed the WHODAS 2.0 questionnaire before their outpatient visit and again after a one-month follow-up to evaluate changes in their disability.

4.2.2 Medical records (I, II, IV)

Data were collected on participants' age, gender, body mass index (BMI), diagnosed medical conditions, past surgeries, medications, smoking habits, and alcohol use. The primary cause of dysphagia was determined based on medical records, findings from the outpatient visit, and any additional tests, which could include neurology consultations, VFS, or oesophageal evaluations.

4.2.3 Investigations

4.2.3.1 FEES (I, IV)

In FEES, swallowing was assessed using a thin videoendoscope passed through the nose while the patient swallowed various textures and bolus volumes. The tested textures included liquid (water), nectar (blueberry soup), semi-solid (puree), and solid (cookie). The boluses were dyed with food colouring to enhance visualisation. The examination began with small boluses (teaspoon-sized) and progressed to larger ones (up to a tablespoon), adjusted according to the patient's swallowing ability.

In Study I, an experienced ENT specialist or phoniatician, often accompanied by a SLP, or an experienced SLP alone, conducted the FEES. In Study IV, the FEES was performed by a single physician (JK), accompanied by an SLP (TK or RP).

FEES was evaluated using three scales: the Yale Pharyngeal Residue Severity Rating Scale (Neubauer et al., 2015), the Penetration-Aspiration Scale (PAS) (Rosenbek et al., 1996), and the Dysphagia Outcome Severity Scale (DOSS) (O'Neil et al., 1999). Additionally, salivary retention in the vallecula and piriform sinuses, movements of the lateral pharyngeal walls and tongue base, velopharyngeal closure, and vocal fold closure were assessed. In Study I, sensory responses of the arytenoids and epiglottis (evaluated by touching with the endoscope) were also recorded. For the Yale Pharyngeal Residue Severity Rating Scale and PAS, the worst result was recorded as the final score.

4.2.3.1.1 Swallowing guidance (IV)

In Study IV, the potential effect of a one-time intervention involving FEES with swallowing guidance during a 90-minute outpatient visit was evaluated. After conducting the FEES, the physician and SLP reviewed the video recordings with the patient, explaining the anatomy and physiology of swallowing, sometimes with the help of illustrations. Any disruptions in the patient's swallowing function were highlighted in the videos. The most troublesome symptoms were identified, and factors contributing to abnormal swallowing were pinpointed. Facilitating techniques were also recognized and explained.

Patients were encouraged to discontinue any avoidance behaviours and to maintain normal, social eating habits, provided no safety risks were identified during the swallowing assessment. Any fear, anxiety, or misconceptions related to swallowing were addressed, aiming to reduce psychological barriers.

If mucosal dryness was detected, recommendations for humidifying and lubricating the nose and throat were provided. Adjustments to swallowing speed, bolus size, and consistency were suggested when necessary. Postural adjustments or

swallowing techniques, such as the supraglottic swallow or effortful swallow, were demonstrated using FEES biofeedback if deemed effective. In cases of muscle tightness, recommendations for chewing muscle or head and neck massages were given, along with self-treatment instructions. Swallowing exercises or therapies, such as thermal or electrical stimulation, were not provided. Patients received written instructions covering all guidance. This intervention is referred to as 'swallowing guidance' to distinguish it from more intensive swallowing therapy.

4.2.3.2 100 ml Water Swallow Test (I, II, IV)

WST was conducted according to DePippo et al. (1993) in Study I and according to Wu et al. (2004) in Study II. In Study I, patients were instructed to drink 100 ml of water continuously at their own pace, while in Studies II and IV, they were instructed to drink as quickly as possible without pausing. The WST was considered successful if the patient did not cough during or within 1 minute after drinking, and if there was no interruption in drinking (such as removing the glass from the lips) or any post-swallow wet-hoarse voice.

In Study II, individual parameters of the WST were evaluated, including average bolus size and swallowing speed. The average bolus size was calculated by dividing 100 ml (or 100ml minus any residual water in the case of interrupted drinking) by the number of swallows (Studies II, IV). A bolus size greater than 20 ml (completing 100 ml in fewer than five swallows) was considered normal (Adnerhill et al., 1989). The time from the start of swallowing to the completion of the drinking process (when the larynx returned to its resting position after the final swallow) was measured in seconds, and swallowing speed (ml/s) was determined by dividing 100 ml (or the amount consumed in the case of interrupted drinking) by the total drinking time. A swallowing speed of over 10 ml/s was considered normal (Nathadwarawala et al., 1992).

In Study IV, we used a simplified version of the WST, the sWST, which was introduced in Study II. In the sWST only coughing and average bolus size were observed.

4.2.3.3 Videofluoroscopy (II, III)

4.2.3.3.1 Imaging protocol

VFS was imaged using a twin robotic X-ray system (Multitom Rax, Siemens Healthcare GmbH, Erlangen, Germany) with a tube voltage of 73 kV and a 0.2 mm Cu filter. Imaging was typically performed at 15 pulses/second following the ALARA ("as low as reasonably achievable") principle to minimize radiation

exposure. However, 30 pulses per second in continuous mode were used when further clarification was needed. The contrast medium used was an oral iodine-based iohexol (Omnipaque 300 mg/ml, GE Healthcare, Princeton, New Jersey), chosen for its safer profile compared to barium, particularly in cases of aspiration, its IDDSI 0 viscosity, and its reduced tendency to leave residue.

The imaging protocol is described in Table 4.

Table 4. Videofluoroscopy imaging protocol.

ORAL IOHEXOL BOLUS	BOLUS VOLUME	OROPHARYNGEAL IMAGING	OESOPHAGEAL IMAGING
LIQUID (IDDSI 0)	10 ml	Lateral Anterior-posterior	Oblique Anterior-posterior
	20 ml	Lateral	-
MODERATELY THICKENED (IDDSI 3)	10 ml	Lateral Anterior-posterior	- Anterior-posterior
COOKIE-IOHEXOL MIXTURE	10 ml	Lateral Anterior-posterior	- Anterior-posterior

IDDSI= International Dysphagia Diet Standardisation Initiative Framework

VFS began with a 10 ml thickened iodine bolus, which patients were instructed to swallow in one go, with lateral, oblique, and anterior-posterior (AP) views captured. Thickened consistencies are generally regarded as safer for swallowing compared to liquids due to their slower flow rate and reduced risk of aspiration. Therefore, the examination was initiated with a thickened bolus to minimize the potential for aspiration in this standardized imaging protocol. The liquid iodine contrast was thickened using a xanthan gum-based thickener (Resource ThickenUP Clear, Nestlé Health Science, Vevey, Switzerland) to achieve an IDDSI 3 consistency. Thoracic oesophagography was included in the oblique and AP views.

The procedure continued with a 10 ml liquid iodine bolus (IDDSI 0), also swallowed in one go, imaged in lateral and AP views. Finally, patients consumed a spoonful of an iodine-coated cookie mixture, which was imaged in lateral and AP views. Additionally, 76 patients were tested with a 20 ml liquid bolus, and penetration/aspiration results were compared with those from the 10 ml liquid bolus. If contrast residue was detected, patients were instructed to clear their throat with water before proceeding. All images were stored in the imaging server at Turku University Hospital (Philips Vue PACS).

4.2.3.3.2 VFS ratings

In Study II, an experienced radiologist (JV), blinded to the EAT-10 and WST results, analysed the VFS findings both in real time and later using slow-motion or frame-by-frame review. The VFS findings were categorized using a modified version of the GLUPS score (Lechien, Cavelier, et al., 2019), with data recorded on the Videofluoroscopy Finding Form (Appendix 1a,1b). The results were classified into three categories:

- Oral findings: lip closure, tongue movement, premature pharyngeal spillage, oral residue
- Pharyngeal findings: swallow onset, velopharyngeal closure, epiglottal retroflexion, laryngeal elevation, vallecular or pyriform sinus residue, penetration/aspiration
- Oesophageal findings: UES opening, oesophageal peristalsis, oesophageal stasis, LES function

Each of the 15 criteria was classified as normal or abnormal. Penetration and aspiration were further graded using the Penetration-Aspiration Scale (PAS), with PAS scores of 2–5 indicating penetration and scores of 6–8 indicating aspiration (Rosenbek et al., 1996).

In Study III, the subjective normal-abnormal ratings described above were also performed by an ENT doctor and a phoniatician (JK) who filled out the Videofluoroscopy Finding Form without access to the radiologist's scoring.

Objective analyses for Study III were conducted 9–15 months after the initial subjective evaluations, with two raters blinded to the subjective ratings. All lateral VFS images of liquid bolus consistencies were analysed using Swallowtail software (Belldev Medical, Chicago, USA, versions 3 and 4), a tool designed for quantitative videofluoroscopic analysis. The most pathological image series, using either a 10 ml or 20 ml bolus, was selected for analysis by two experienced radiologists (JV and JH). The following parameters were measured: pharyngeal aerated area during bolus holding (PAhold), maximum pharyngeal area during swallowing (PAm_{ax}), pharyngeal constriction ratio (PCR), maximum pharyngoesophageal segment opening (PES_{max}), pharyngoesophageal segment opening duration (POD), airway closure duration (ACD), and total pharyngeal transit time (TPT), in accordance with previously published methodologies (Kendall, 2000; Leonard, 2019; Leonard et al., 2011; Leonard et al., 2000; Park et al., 2010; Regueiro et al., 2017). Normative values for most measurements were referenced from Leonard and Kendall's work (2017), with deviations of more than two standard deviations (SD) from the mean considered abnormal. Normative PCR values were sourced from Leonard et al.'s publication (2011).

4.3 Statistical analysis

All statistical calculations were made with the IBM SPSS Statistics for Windows (Versions 26.0–29.0; IBM Corp., Armonk, Ny, USA). *P* values less than 0.05 were considered statistically significant. Statistical analyses were carried out with consultation from an experienced statistician.

4.3.1 Sample size

The minimum sample size for Study I was set at 100 participants for both the FEES patients and controls, based on a subject-to-item ratio of 10:1. To account for a potential 10% dropout rate, the required sample size was increased to 111 participants.

Study II aimed to assess whether the EAT-10 (a patient-reported outcome measure) and the WST (a swallowing performance screener) could predict normal or abnormal findings, as well as penetration/aspiration, in VFS. Sample size calculations were based on different sensitivity and specificity estimates, assuming an 80% prevalence of dysphagia in VFS. With a specificity of 0.70, margin of error of 0.20, and a 10-20% dropout rate, the estimated sample size was 120 participants. Additionally, a cross-sectional analysis of VFS examinations over one year, incorporating objective analysis (Study III) into the study protocol, led to an increased sample size of 150 for Study II and 77 for Study III.

For Study IV, the sample size was calculated based on anticipated changes in EAT-10 total scores from baseline to a one-month follow-up, using the Wilcoxon signed-rank test. With an estimated score decrease of 2, the required sample size was 54, which was adjusted to 60 to account for a 10% dropout rate.

4.3.2 Statistical methods

In Studies I and II, EAT-10 scores were presented as means (standard deviation, SD) for clarity and comparability with other studies, despite the non-normal distribution of data. In Study IV, however, EAT-10 total scores were reported as medians due to the data distribution. Other results, such as age, were reported as frequencies, medians (range), or means (SD), depending on the data distribution.

In Study I, internal consistency and reliability of the EAT-10 were analysed using data from both controls and FEES patients. Cronbach's alpha was used to evaluate the internal consistency of the baseline EAT-10 questionnaire, both for the combined group and for FEES patients alone. Values between 0.7 and 0.8 indicated acceptable consistency, between 0.8 and 0.9 good consistency, and values ≥ 0.9 indicated excellent consistency (George & Mallery, 2005).

Test-retest reliability in Study I was assessed using two methods: the Pearson correlation coefficient and the intraclass correlation coefficient (ICC). Pearson correlation values <0.3 were considered weak, 0.3 to 0.49 moderate, and ≥ 0.5 strong (Ventura, 1988). ICC was calculated using a two-way mixed-effects model, with values below 0.50 considered poor, between 0.50 and 0.75 fair, between 0.75 and 0.90 good, and above 0.90 excellent (Koo & Li, 2016). ICC was also used to assess agreement between objective measures in Study III.

The Mann-Whitney U test was used to compare median age differences between FEES patients and controls, and gender distribution differences were evaluated using the chi-square test (Study I). Correlations between age and EAT-10, VFS, and WST findings were assessed with Spearman's rho and Mann-Whitney U-tests (Studies I, II, IV). The effect of gender on VFS and WST findings, or symptom changes was analysed using chi-square tests (Studies I, II, IV). Mann-Whitney U tests were also applied to compare individual EAT-10 question scores and total scores between FEES patients, operative patients, and controls (Study I).

Spearman's rho was used to correlate baseline EAT-10 scores with various clinical findings, including PAS scores, Yale Pharyngeal Residue Rating Scale, DOSS, and other status findings (Study I) or VFS findings (Study II). Comparisons between EAT-10 scores and FEES findings were conducted using Mann-Whitney U or Kruskal-Wallis tests (Study I). The ROC curve with the Youden Index was used to identify the EAT-10 score threshold for aspiration or penetration in FEES (Study I). Changes in subjective symptoms were compared with EAT-10 score changes using the Kruskal-Wallis test, while changes in the operative group (Study I) or outpatient cohort (Study IV) were analysed with the Wilcoxon signed-rank test.

The relationship between WST and VFS results was analysed using chi-square or Fisher's exact tests (Study II), and sensitivities, specificities, and likelihood ratios (LR+ and LR-) were calculated.

In Study III, inter-rater reliability for subjective normal-abnormal ratings was assessed using Cohen's kappa with 95% confidence intervals (CI). Kappa values were interpreted as follows: 0.0 – 0.20 (no agreement), 0.21 – 0.39 (minimal), 0.40 – 0.59 (weak), 0.60 – 0.79 (moderate), 0.80 – 0.90 (strong), and >0.90 (almost perfect) (McHugh, 2012). Fisher's exact test was used to examine associations between objective measurements and subjective ratings of pharyngeal phase abnormality, penetration/aspiration, or cricopharyngeal relaxation.

In study IV, HRQoL was evaluated by comparing baseline 15D scores to an age- and gender-matched sample from the Finnish population, using an independent samples t-test. Changes in WHODAS 2.0 domain and total scores between the initial visit and follow-up were analysed using the Wilcoxon signed-rank test. Post hoc analyses to compare 15D means between different aetiology subpopulations were carried out using one-way ANOVA with Bonferroni corrections.

4.4 Ethical considerations and funding

Each study was conducted in accordance with the guidelines of the Declaration of Helsinki (The World Medical Association 2013). Study I received approval from the Ethics Committee of the Hospital District of Helsinki and Uusimaa (HUS/1125/2018), while Studies II–IV were approved by the Ethics Committee of Southwest Finland (II–III: ETMK Dnro: 39/1801/2021; IV: ETMK Dnro: 63/1801/2021). As a nationwide multicentre study, Study I also obtained approval from each participating hospital district (the Hospital District of Southwest Finland: T06/031/18). For Studies II–IV, approval was granted by the Clinical Research Centre of the Hospital District of Southwest Finland (II–III: T06/019/21; IV: T06/030/21). Prior to participation, all patients were given both verbal and written information and were required to provide written consent.

The individuals recruited for the dissertation studies were patients undergoing examinations and treatments as part of their medical care and received no separate compensation for participating in the research. The visits, examinations, and treatments for both patients and controls were covered by municipal billing, as no additional research procedures requiring funding were conducted for these studies. The researchers received no payment for their participation; data were collected during routine patient care. Grants were applied for to cover research leave needed for analysing the results and writing the articles and thesis.

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5 Results

5.1 EAT-10 in clinical use

5.1.1 Translation and validation in Finnish (I)

Study I demonstrated that the Finnish version of the EAT-10 is a reliable and valid tool for assessing dysphagia among Finnish speakers.

5.1.1.1 Normative data and feasibility

Analysis was conducted on baseline questionnaires from 180 controls. The median time for controls to complete the EAT-10 was 30 seconds (range 10–120 seconds), indicating its feasibility. The mean total score was 0.47 (SD 0.96, range 0–6). The cut-off for normal was determined by adding +2 SD to the mean, rounding it up to 3. In controls, the cut-off score ≥ 3 demonstrated high sensitivity (94.0%) and specificity (96.1%), indicating the presence of dysphagia.

5.1.1.2 Clinical validity

Analysis was conducted with 117 FEES-patients and 180 controls. There were no significant differences in gender distribution between the control group and FEES patients. Although FEES patients were older than controls ($p < 0.001$), age did not show a significant correlation with the baseline EAT-10 total score in either the control group ($p = 0.17$) or FEES patients ($p = 0.24$). However, for EAT-10 Item 3, which concerns swallowing liquids, age was correlated with a higher score in FEES patients ($p = 0.002$). FEES patients had significantly higher total and individual question scores compared to controls, with all differences reaching statistical significance ($p < 0.001$).

5.1.1.3 Internal consistency and reliability

Analysis was determined using data from acceptable baseline questionnaires of 117 FEES patients and 180 controls, among which 92 FEES-patients and 123 controls

had acceptable re-test questionnaires. The internal consistency of the EAT-10 total score, measured by Cronbach's alpha, was excellent (0.95) for the combined group of FEES patients and controls, and good (0.88) for FEES patients alone. Test-retest reliability, assessed using the ICC, was excellent for the combined group (0.93, 95% CI 0.91–0.95) and good for FEES patients alone (0.84, 95% CI 0.76–0.89). Pearson correlation coefficients for individual questions and the baseline EAT-10 total scores were statistically significant ($p<0.001$) for both FEES patients and the combined group. Pearson correlations were strong for the total baseline EAT-10 score and for each question in both groups combined, as well as for FEES patients alone.

5.1.1.4 Criterion validity

To assess criterion validity, the baseline EAT-10 total scores of 117 FEES patients were compared with their clinical findings. Several correlations were found, including with saliva retention in the vallecula and pyriform sinuses ($p<0.001$) and lateral pharyngeal wall movements ($p=0.02$). However, no significant differences were identified between the EAT-10 total score and normal versus abnormal findings in velopharyngeal closure, tongue base movement, vocal fold closure, or sensory testing on the epiglottis tip or arytenoids. A negative correlation was observed between the DOSS and baseline EAT-10 total scores ($p<0.001$), indicating that patients on a normal diet (DOSS 7) had the lowest EAT-10 total scores.

There was also a statistically significant difference ($p=0.04$) in EAT-10 total scores between those who passed the WST and those who did not (EAT-10 total scores 14.0 (SD 8.4) and 18.2 (SD 9.3), respectively). Furthermore, those who coughed while drinking had significantly higher EAT-10 total scores ($p=0.001$), with a mean of 23.0 (SD 8.0) compared to 13.8 (SD 8.3) for those who did not cough.

Out of the 22 surgical patients, 21 (95.5%) returned the follow-up questionnaire. Among them, 19 completed all the questions, including the one about symptom changes following the operation. The mean EAT-10 score was 21.8 (SD 6.3, range 11–35) at baseline and 11.4 (SD 10.0, range 0–31) after the 3-month follow-up, with a statistically significant change in scores ($p<0.001$). Most patients reported being either asymptomatic ($n=10$, 52.6%) or having fewer symptoms ($n=8$, 42.1%) after the operation. One patient (5.3%) felt their symptoms remained unchanged, and no patients reported worsening symptoms.

The median EAT-10 score decreased by 7.0 for those with fewer symptoms and by 17.5 for those who became asymptomatic. The score remained the same for the patient with unchanged symptoms. However, likely due to the small sample size, this result was not statistically significant ($p=0.31$). In conclusion, changes in EAT-10 scores reflected changes in subjective symptoms for operative patients.

5.1.2 EAT-10 total scores according to aetiology (I, II, IV)

Table 5 shows the variability in EAT-10 total score means between different aetiologies.

5.1.3 EAT-10 as screening tool for VFS (II)

Analysis was conducted on 150 consecutive patients who completed the EAT-10 and underwent the WST before VFS. EAT-10 scores were higher in patients who failed the WST ($p=0.004$), had slow swallowing ($<10\text{ml/s}$) ($p=0.009$), or showed abnormalities in the oral ($p=0.004$), pharyngeal ($p=0.042$), or oesophageal phase ($p=0.032$) on VFS. Patients failing any WST parameter also had higher EAT-10 scores, though the difference was not statistically significant. Overall, WST and VFS test results did not show a significant correlation with EAT-10 scores. Combining WST with EAT-10 did not improve accuracy in predicting VFS results.

5.1.4 EAT-10 as predictor of penetration or aspiration (I, II)

In Study I, the optimal cut-off for predicting penetration or aspiration in FEES patients was obtained using the ROC curve and the Youden Index. The EAT-10 cut-off score for liquid aspiration in the PAS was 22, with a sensitivity of 54.5% and specificity of 19.2%. For penetration or aspiration, the cut-off was 16 (sensitivity 70.4%, specificity 42.0%). The cut-off for nectar penetration or aspiration was 22 (sensitivity 57.9%, specificity 17.5%), while for puree, it was 16 (sensitivity 68.4%, specificity 45.4%), and for cookie, it was 16 (sensitivity 61.9%, specificity 42.5%).

In Study II the analysis was based on the EAT-10 cut-off 16, which has been previously published as predictive of penetration or aspiration (Cheney et al., 2014). Among 150 patients who underwent VFS, 95 had EAT-10 scores <16 and 55 had scores ≥ 16 . An EAT-10 score <16 predicted no penetration/aspiration on VFS with 67.4% specificity, while a score ≥ 16 predicted penetration/aspiration with 84.6% sensitivity (LR+ 2.595, LR- 0.228, $p<0.001$).

Table 5. Aetiology of dysphagia and mean Eating Assessment Tool (EAT-10) total scores in Studies I, II, and IV.

AETIOLOGY	STUDY I FEES-patients n (%), EAT-10 MEAN (SD)	STUDY II n (%), EAT-10 MEAN (SD)	STUDY IV baseline n (%), EAT-10 MEAN (SD)
FUNCTIONAL	31 (26.5%), 16.2 (9.7)	11 (7.3%), 16.0 (8.0)	15 (25.0%), 21.9 (9.9)
HEAD AND NECK OR OESOPHAGEAL CANCER	16 (13.7%), 22.3 (6.6)	3 (2.0%), 16.0 (7.0)	1 (1.7%), 24.0 (-)
NEUROLOGICAL	15 (12.8%), 17.4 (9.9)	17 (11.3%), 16.0 (7.0)	8 (13.3%), 17.2 (6.8)
OESOPHAGEAL*	14 (12.0%), 14.5 (9.1)	47 (31.1%), 14.0 (9.0)	7 (11.7%), 19 (11.2)
PRESBYPHAGIA	12 (10.3%), 13.8 (7.9)	9 (6.0%), 13.0 (8.0)	5 (8.3%), 14.6 (7.9)
DRY MOUTH/THROAT	9 (7.7%), 13.2 (5.0)	20 (13.2%), 11.0 (7.0)	9 (15.7%), 12.7 (11.2)
NORMAL	9 (7.7%), 6.2 (5.0)	6 (4.0%), 5.0 (5.0)	-
COMPRESSION**	3 (2.6%), 13.3 (11.0)	6 (4.0%), 12.0 (9.0)	5 (8.3%), 12.8 (8.0)
CRICOPHARYNGEAL PROBLEM OR ZENKER'S DIVERTICULUM	4 (3.4), 20.5 (8.2)	26 (17.2%), 13.0 (7.0)	-
GASTRIC (STUDY II)	-	3 (2.0 %), 8.0 (9.0)	-
GLOBUS (STUDY IV)	-	-	10 (16.7%), 13.5 (9.0)
OTHER***	4 (3.4%), 12.0 (9.5)	3 (2.0), 20.0 (16.0)	-

* reflux, motility disorders, esophagitis

** goiter, osteophyte, surgical material after anterior cervical interbody fusion

*** Ehlers-Danlos syndrome, overlap myositis, dermatomyositis, scleroderma, operated cleft palate, sialolith

Table 6. Water Swallow Test (WST) parameters and their associations with Videofluoroscopy (VFS) findings. Modified from Study II.

		VFS normal n/% within normal	VFS abnormal n/% within abnormal	p- value
COUGHING DURING DRINKING	no	39/100%	103/92.8%	0.112
	yes	0	8/7.2%	
COUGHING AFTER DRINKING	no	35/89.7%	85/76.6%	0.077
	yes	4/10.3%	26/23.4%	
COUGHING BOTH	no	35/ 89.7%*	82/73.9%*	0.040*
	yes	4/10.3%*	29/26.1%*	
WET HOARSE VOICE AFTER DRINKING	no	39/100%	109/98.2%	1.000
	yes	0	2/1.8%	
AVERAGE DRINKING BOLUS SIZE	>20 ml	16/41.0%*	23/20.9%*	0.014*
	≤20 ml	23/59.0%*	87/ 79.1%*	
SWALLOWING SPEED (SS)	>10 ml/s	27/69.2%	47/42.3%	0.004*
	<10 ml/s	12/30.8%	64/57.7%	
WST NORMAL (WITHOUT SS)	yes	32/ 82.1%*	66/59.5%*	0.011*
	no	7/17.9%*	45/40.5%*	
WST NORMAL (WITH SS)	yes	23/59.0%*	39/35.1%*	0.009*
	no	16/41.0%*	72/64.9%*	
SIMPLIFIED WST NORMAL	yes	15/38.5%*	18/16.2%*	0.004*
	no	24/61.5%*	93/ 83.8%*	

Statistically significant results are marked with an asterisk (*) The most sensitive and most specific results are bolded. In simplified WST, only coughing and average bolus size are evaluated. SS=swallowing speed.

5.2 Water Swallow Test in clinical use (II)

Study II found that in the WST, the absence of coughing was the most specific predictor (89.7%) of normal VFS findings, while a bolus size ≤20 ml was the most sensitive predictor (79.1%) of abnormal findings. Table 6 presents the results of WST parameters and their associations with VFS findings. Combining coughing with a bolus size ≤20 ml (simplified WST, sWST) increased sensitivity to 83.5% for detecting abnormal results.

The most sensitive predictor of penetration/aspiration was failing any WST parameter (84.6%), while the absence of coughing indicated no penetration/aspiration (82.5% specificity). Combining WST with EAT-10 did not improve accuracy in predicting VFS results.

5.3 Bolus size in videofluoroscopy (II)

In Study II, we tested both 10-ml and 20-ml liquid boluses (IDDSI 0) in VFS for 76 patients. Six patients exhibited penetration/aspiration with the 10-ml bolus, while 12 showed it with the 20-ml bolus. Notably, nine patients (11.8% of the total) had no penetration/aspiration with the smaller bolus, suggesting that the 20-ml liquid bolus was more sensitive in detecting penetration/aspiration than the 10-ml bolus ($p=0.005$).

5.4 Ratings in videofluoroscopy (III)

Study III showed that inter-rater agreement on subjective pharyngeal findings was moderate to strong, particularly for residues (κ -values ranging from 0.653 to 0.855, 95% CI 0.460–0.995, $p<0.001$) and penetration/aspiration (κ -values from 0.661 to 0.708, 95% CI 0.027–1.295, $p<0.001$). Inter-rater agreement was weaker for rating the oral and oesophageal findings.

Objective measurements showed fair to good inter-rater agreement. Statistically significant associations were found between certain objective measures, including pharyngeal phase abnormality and total pharyngeal transit time (TPT), normal cricopharyngeal relaxation with normal PESmax, and normal PCR and the absence of penetration/aspiration.

5.5 FEES with swallowing guidance (IV)

Study IV revealed significant reductions, indicating fewer symptoms, in EAT-10 scores among all dysphagia patients and in the functional dysphagia subgroup after one month ($p=0.020$ and $p=0.029$, respectively), as shown in Figure 9. The 15D scores at the one-month follow-up were also higher, suggesting improved HRQoL, in the functional dysphagia, dry mouth/throat, cervical osteophyte, and globus groups. However, no significant changes were observed in the 15D or WHODAS 2.0 total scores, likely due to the small sample size within each diagnostic subgroup (data not shown). Functional dysphagia patients showed significant improvement in the WHODAS 2.0 eating-related item ($p=0.020$).

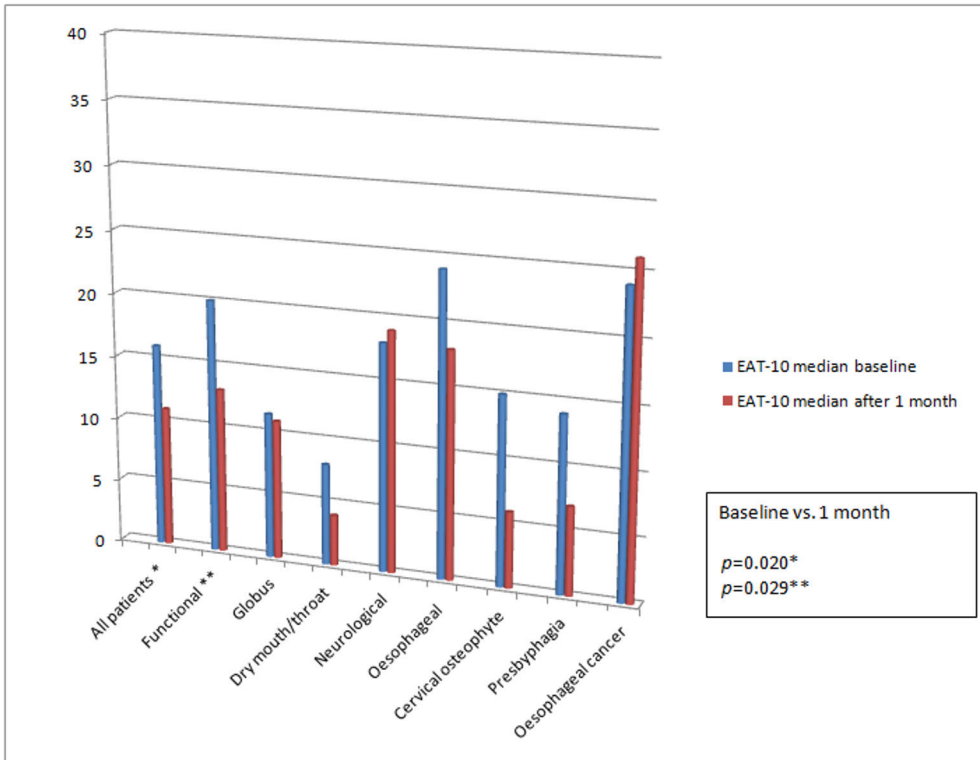


Figure 9. EAT-10 total score medians at baseline and one month after swallowing guidance by dysphagia aetiology. Modified from Study IV.

5.6 HRQoL in dysphagia patients (IV)

Overall, dysphagia patients had significantly lower 15D scores, indicating worse HRQoL compared to the age- and gender-matched general Finnish population. Significant differences were observed across 12 of the 15 dimensions ($p<0.001$).

6 Discussion

6.1 Finnish version of EAT-10

Our results from Study I confirm that the Finnish version of the EAT-10 is a valid PROM for assessing dysphagia. There were no missing answers from controls, indicating that the Finnish version of the EAT-10 was easy to complete, with a median completion time of 30 seconds. The Cronbach's alpha for the EAT-10 was 0.95 for both controls and FEES patients combined, and 0.84 for FEES patients alone, indicating excellent internal consistency. This is consistent with other EAT-10 validation studies (Abu-Ghanem et al., 2016; Belafsky et al., 2008; Burgos et al., 2012; Demir et al., 2016; Frajkova et al., 2022; Giraldo-Cadauid et al., 2016; Lechien, Cavelier, et al., 2019; Möller et al., 2016; Nogueira et al., 2015; Schindler et al., 2013).

Test-retest reliability, measured by ICC, was 0.93 for all participants and 0.84 for FEES patients alone, showing strong reproducibility. Pearson correlations were also strong for both total scores and individual questions. Higher ICCs and correlations have been published (Abu-Ghanem et al., 2016; Giraldo-Cadauid et al., 2016; Schindler et al., 2013). It is possible, that our re-test results differ because FEES itself is an intervention, which may alleviate symptoms, as observed in Study IV.

The mean EAT-10 total score varied by diagnosis as shown in Table 5. Criterion validity revealed weak correlations between EAT-10 total scores and FEES findings, but stronger correlations were observed with the DOSS and PAS scores. The EAT-10 effectively captured symptom changes over a 2-week (for FEES-patients) or 3-month (for operative patients) follow-up, supporting its use for tracking symptoms over time.

6.2 EAT-10 and WST as screening tools

Study I showed significant differences between dysphagia patients and controls in EAT-10 total scores and individual questions, supporting its use as a screening tool for detecting dysphagia. Most controls had scores of 0, with a mean score of 0.47, consistent with prior studies (Abu-Ghanem et al., 2016; Belafsky et al., 2008; Burgos

et al., 2012; Frajkova et al., 2022; Giraldo-Cadavid et al., 2016; Lechien, Cavellier, et al., 2019; Möller et al., 2016; Nogueira et al., 2015; Printza et al., 2018; Schindler et al., 2013). A cut-off score of <3 was determined for controls, as in many other validation studies (Belafsky et al., 2008; Frajkova et al., 2022; Möller et al., 2016; Nogueira et al., 2015; Schindler et al., 2013), although some studies suggest a cut-off of 2 (Giraldo-Cadavid et al., 2016; Rofes, Arreola, Mukherjee, et al., 2014).

In Study I, we also examined whether the EAT-10 could predict aspiration risk. A cut-off score of ≥ 16 indicated penetration (PAS >1), although sensitivity and specificity were lower than those reported by Cheney et al. (2014), likely due to the small number of patients with penetration or aspiration. Previous studies have concluded that high EAT-10 scores can predict aspiration (Arslan et al., 2017; Bartlett et al., 2022; Giraldo-Cadavid et al., 2016; Lechien et al., 2019); however, contradictory findings have also been reported (Kendall, 2016). These discrepancies may stem from the heterogeneity of the studies. As demonstrated in our studies, the aetiology of dysphagia significantly influences EAT-10 scores, making it challenging to establish thresholds for specific clinical features, such as aspiration.

Study II focused on whether the EAT-10 and WST could predict findings in VFS and serve as screening tools for referral to VFS. We also investigated the individual qualitative and quantitative parameters of the WST as potential predictors. To our knowledge, the individual parameters of the WST have not been studied to this extent before. Coughing and average drinking bolus size were as key predictors of normal and abnormal VFS results. Absence of coughing had 89.7% specificity for predicting a normal VFS, while a drinking bolus size of ≤ 20 ml was the most sensitive predictor of abnormal VFS findings (79.1%).

We further explored which parameters of the WST were the most sensitive or specific for detecting penetration or aspiration findings in VFS. The strongest predictor for the absence of penetration/aspiration in VFS was the absence of coughing during the WST, with a specificity of 96.4% (coughing after drinking had a specificity of 83.9% and coughing during or after drinking had a specificity of 82.5%). The most sensitive predictor of penetration/aspiration in VFS was failing any WST parameter, with a sensitivity of 84.6%. Including the swallowing speed measurement did not improve sensitivity; however, it reduced specificity from 70.1% (without swallowing speed) to 43.8% (with swallowing speed).

Therefore, we introduced the simplified WST (sWST), which focuses on coughing and bolus size, as a sensitive tool (83.8%) for predicting abnormal VFS findings, though its clinical applicability requires further study. Voice changes and swallowing speed were less useful and, based on our results, could be excluded from WST interpretation.

In Study I, WST results showed significant differences in EAT-10 scores between patients who passed or failed, and between those who coughed and those

who did not, suggesting that WST and EAT-10 together may predict swallowing issues. In Study II, combining WST results with EAT-10 (cut-off ≥ 16) increased sensitivity but reduced specificity for predicting abnormal VFS results. WST alone, or sWST, was more effective in enhancing specificity, while combining WST with EAT-10 results improved sensitivity for detecting penetration/aspiration. WST focuses on swallowing efficacy and safety, while EAT-10 assesses symptom severity and the impact of dysphagia, making them complementary but distinct tools.

6.3 VFS ratings

VFS is the gold standard for dysphagia evaluation, but it lacks standardization, leading to variability in interpretations. In Study III, we found moderate agreement between raters on normal-abnormal findings, with the highest agreement on pharyngeal residue and penetration/aspiration, which are key indicators of swallowing efficacy and safety. Thus, at a minimum, standardized normal-abnormal ratings should be used, and these have already been implemented in practice at Turku University Hospital, as outlined in Videofluoroscopy Finding Form (Appendix 1a, 1b).

Subjective ratings for oral and oesophageal findings had weak agreement, which could improve with additional training (Scott et al., 1998). Although objective measurements demonstrated fair to good reliability, they require expertise for proper interpretation. Leonard and Kendall's research links certain measurements, such as pharyngeal dilatation and TPT, to specific swallowing issues. However, many of our objective measures, such as PCR, showed poor reproducibility. Normal PCR correlated with the absence of penetration/aspiration, but other measurements had uncertain clinical value.

Overall, objective measures exhibited better inter-rater reliability than subjective ratings. We observed correlations between TPT and pharyngeal phase abnormalities, normal PCR and the absence of penetration/aspiration, and normal PESmax and normal cricopharyngeal relaxation. However, the clinical relevance of other objective measures was limited. Although prolonged TPT has been associated with an increased risk of aspiration (Johnson et al., 1992, 1993; Rademaker et al., 1994), we found no direct link between TPT and penetration/aspiration, making it difficult to assess its role in predicting swallowing safety. Moreover, delayed TPT has also been noted in healthy adults (Butler et al., 2011; Kendall & Leonard, 2001). These measurements may more accurately reflect a risk for future swallowing problems rather than current ones.

6.4 Bolus size in swallowing examinations

In Study II, the 20 ml bolus was more effective in detecting penetration/aspiration on VFS than the 10 ml bolus. In the WST, counting swallows and assessing whether the average bolus size was above or below 20 ml proved useful, as described earlier. In healthy adults, the normal size for a thin liquid bolus was found to be 21 ml (SD ± 5 ml) (Adnerhill et al., 1989). Therefore, limiting bolus size to 10 ml or less in VFS does not accurately represent normal swallowing behaviour.

While a standardized approach like MBSImp can improve the objectivity of VFS interpretation, the small volumes it uses (3–5 ml) do not reflect typical swallowing patterns and focus mainly on the oropharyngeal phase, with limited assessment of oesophageal clearance. Additionally, MBSImp requires licensed training for proper implementation.

6.5 VFS protocol

The European Society for Swallowing Disorders (ESSD) stated at the Second ESSD Congress (Barcelona, 25 October 2012) that VFS should be conducted in a standardized manner, preferably with the patient in an upright position. VFS must always include a lateral view of the oral cavity, pharynx, and oesophagus. The test should focus on the patient's worst swallow to detect dysfunctions or morphological abnormalities that explain their symptoms. A range of viscosities and textures, including thin liquid, puree, and soft solid (if deemed safe), should be used. A dysphagia specialist and a radiologist should jointly perform the VFS, with a capture rate of at least 25 frames per second (Delahaut & Van der Vorst, 2019).

At Turku University Hospital, VFS is commonly performed at 15 frames per second, which, based on our experience, is sufficient to detect abnormalities. If abnormalities are identified, we switch to a continuous mode at 30 frames per second to detect more subtle issues. The imaging protocol is outlined in Table 4. The consistencies used include liquid (IDDSI 0), moderately thick liquid (IDDSI 3), and a moistened cookie with contrast agent (IDDSI 5–7). For safety reasons, the protocol for Studies II and III was standardized to begin with IDDSI 3, followed by thin liquid. The 20 ml liquid bolus challenge was found to be effective in detecting potential aspiration. As a result, the imaging protocol at Turku University Hospital has been modified to include this 20 ml liquid challenge.

Iodine contrast agent (iohexol, Omnipaque 300 mg/ml, GE Healthcare, Princeton, New Jersey) was used in our standardized protocol due to its IDDSI 0 consistency, whereas many barium products have a consistency of IDDSI 1–3. Additionally, it is water-soluble, making it safer than barium in cases of aspiration.

While including a wider range of bolus sizes and viscosities would provide more comprehensive information from VFS, it would also increase radiation exposure,

which conflicts with local ALARA principles. In this protocol, and using modern fluoroscopic imaging techniques, Dose Area Product (DAP) values for VFS are on average between 50–200 $\mu\text{Gy}\cdot\text{m}^2$ (comparable to thoracic X-ray values for anteroposterior and lateral imaging), with Kinetic energy Released per unit Mass of air by radiation (Air Kerma) values between 5–15 mGy (compared to median 0.12 mGy for anteroposterior thoracic X-ray and median 0.56 mGy for lateral thoracic X-ray), making follow-up VFS feasible when necessary (Metaxas et al., 2019).

6.6 FEES with swallowing guidance and HRQoL

In Study IV, patients with functional dysphagia showed significant improvement in symptoms following a single intervention of FEES with swallowing guidance. This improvement was reflected in reduced EAT-10 total scores and WHODAS 2.0 scores related to eating difficulties one month after the intervention. Dysphagia had a notable negative effect on HRQoL, as assessed by the 15D, when compared to the normative values of the Finnish population. These findings are consistent with research conducted in other countries (Bendsen et al., 2022; Ekberg et al., 2002; Jones et al., 2018).

While the functional dysphagia group benefited from FEES with swallowing guidance, patients with neurological dysphagia did not experience similar improvements, likely due to disease progression. Although median EAT-10 scores suggested potential benefits across various types of dysphagia, statistical significance was not reached, possibly due to small group sizes. The majority of patients reported no change in their symptoms post-intervention, with the exception of 66.6% of xerostomia patients who noted symptom improvement.

To our knowledge, the 15D has been used in only two previous dysphagia studies. Tervonen et al. (2007) examined the effects of anterior cervical decompression on swallowing and vocal function, finding significantly worse baseline 15D scores in patients compared to a control group ($p = 0.028$). However, by the 3-month follow-up after the surgery, the scores had improved and no longer differed significantly from the control group or general population (Tervonen et al., 2007). Järvenpää et al. (2019) studied patients with globus symptoms, reporting improvement in one 15D dimension (discomfort and symptoms) at a 4-month follow-up after diagnosis with ENT and instrumental examinations, despite no specific treatment being administered. In Study IV, globus patients did not show a clear response to swallowing guidance at the one-month follow-up. This lack of response is likely due to globus being primarily associated with muscle tension and stress rather than actual dysphagia, and it needs a longer time to improve. Alternatively, the lack of a significant response might be attributed to the small sample size. Nevertheless, the 15D mean scores showed improvements, albeit not

statistically significant, indicating positive trends in HRQoL across the functional, dry mouth/throat, cervical osteophyte, and globus groups.

The literature on the therapeutic effects of FEES and swallowing guidance, especially for functional dysphagia, remains limited. However, some case studies have been published. For instance, Thottam et al. reported that three of five children (ages 5–15 years) with ‘psychogenic dysphagia’ (defined as food avoidance and excessive fear of eating) experienced complete symptom resolution after undergoing FEES (Thottam et al., 2015). Our study supports the notion that FEES can serve as a therapeutic intervention, particularly for functional dysphagia.

6.7 Functional dysphagia

Functional dysphagia, though considered a rare condition in the literature (Baijens et al., 2013; Verdonschot et al., 2019), was found to be the largest aetiology group in our cohort, comprising one-quarter of our unselected dysphagia outpatient population in Studies I and IV. In contrast, the main aetiologies of patients referred to VFS in Study II were primarily oesophageal or cricopharyngeal issues, such as Zenker’s diverticulum, suggesting some diagnostic selection had occurred prior to referral. Functional dysphagia patients in our study showed improvement from a single FEES intervention with swallowing guidance, reflected by significantly reduced EAT-10 and WHODAS 2.0 scores related to eating difficulties one month after the intervention.

Diagnosing functional dysphagia requires a comprehensive history and some instrumental evaluations, such as FEES, to rule out organic or neurological causes. The diagnosis is typically made using the "rule-out" method, as establishing "rule-in" criteria is more challenging. However, based on our experience, Table 1 lists some potential "rule-in" criteria, including difficulty or fear in initiating swallowing, inconsistent symptoms, inappropriate chewing, bolus rolling in the mouth, an illogical diet, discomfort when eating and drinking, and the sensation of food trapped in the throat or chest without any actual residues.

In persistent cases, it is essential to include the oesophagus in the evaluation, as oesophageal transit issues often manifest as pharyngeal symptoms, particularly the sensation of food sticking in the throat (Edwards, 1974; Madhavan et al., 2015; Smith et al., 1998; Wilcox et al., 1995). Progressive symptoms also warrant further investigation, as dysphagia can be an indicator of various neurological diseases (Panebianco et al., 2020).

Screening tools like WSTs are insufficient for distinguishing functional from organic dysphagia. For instance, a study in the Netherlands found that patients with functional dysphagia often exhibited multiple swallows for the same bolus (piecemeal deglutition), a coping mechanism developed over time (Verdonschot et

al., 2019). In our study, we found that functional dysphagia patients tended to take smaller bolus sizes and often failed the WST due to this, which may serve as an indicator of the condition.

Persistent somatic or functional symptoms, such as seen in functional dysphagia, contribute to substantial healthcare costs, comparable to those associated with mental health conditions like depression and anxiety (Konnopka et al., 2012). These costs can be reduced through targeted interventions aimed at both healthcare providers and patients, thereby minimizing unnecessary tests and specialist referrals. Early diagnosis is critical, as it leads to better treatment outcomes (Deary et al., 2007).

The literature on functional dysphagia is still sparse. Baijens et al. (2013) noted that there is insufficient evidence to guide the treatment of functional dysphagia and concluded that a multidisciplinary diagnostic and therapeutic approach — incorporating both medical and psychological assessments— is essential to improve diagnosis, reduce healthcare costs, and minimize iatrogenic risks. This highlights the need for further research with well-designed study protocols.

In our study, we provided a brief, one-time swallowing guidance or ‘mini-intervention’, which is simple to execute and has the potential to benefit many dysphagia patients. This approach is also cost-effective, as it could serve as the sole assessment or even treatment, particularly for patients with functional dysphagia.

6.8 Limitations of the study

One of the most significant limitations across these studies is the heterogenous nature of the dysphagia population and the small number of patients within each subpopulation. As shown in Table 5, the aetiology of dysphagia influences EAT-10 scores, and investigating these subpopulations would require a much larger sample size. Additionally, patients with oesophageal and gastric disorders, alongside oropharyngeal dysphagia, were included, which may have affected the results. Dysphagia often has a multifactorial aetiology, making it artificial to attribute the condition to a single primary cause. Similarly, distinguishing between ‘organic’ and ‘functional’ dysphagia is problematic, as many organic diseases result in functional impairments. Furthermore, oesophageal and gastric problems often present with oropharyngeal symptoms, complicating the distinction between these conditions.

The use of EAT-10 have been questioned due to concerns about its psychometric properties (Cordier et al., 2017; Speyer et al., 2022). We did not incorporate Item Response Theory or Rasch analysis in our validation process. However, as concluded, the primary value of EAT-10 lies in its quick and feasible use to expand anamnesis, rather than as a definitive screening tool for dysphagia.

Another limitation is that all studies included only Finnish-speaking participants, potentially introducing cultural bias. In Studies I and IV, some

questionnaires were excluded due to missing or unclear responses. There was also a discrepancy between changes in EAT-10 scores and patients' subjective reports of symptom changes. In Study I, the number of surgical patients was small, and the follow-up period in Study IV was relatively short. A longer follow-up period might provide better insights into the long-term effects of FEES with swallowing guidance. Conversely, in Study I, the three-month follow-up might have been too long, as assessing symptom changes earlier post-surgery could yield more accurate results.

In Study I, 12 different professionals performed the FEES, which may have influenced the consistency of interpretations. However, the use of established classifications should have enhanced consistency of FEES evaluations. In Studies II, III, and IV, the FEES or VFS ratings were performed by a single professional, sometimes with the involvement of an SLP (as in Study IV), without controlling for intra-rater reliability. Inter-rater reliability was assessed only in Study III.

Study III focused on inter-rater agreement but did not evaluate the actual accuracy of the results. Including three or more raters and assessing intra-rater reproducibility would have strengthened the study. Raters involved in subjective and objective evaluations did not discuss their assessments or undergo joint training, which likely affected the results. However, even well-trained evaluators have shown inconsistencies (Lee et al., 2017). Notably, the ICC between the two experienced radiologists in our study was consistent with the agreement levels reported among trained SLPs (Nordin et al., 2017). The absence of joint training between the radiologists likely reflects typical clinical practice, which enhances the generalizability of the findings.

In Study IV, the small number of patients in each aetiology group made it difficult to determine the precise impact of the swallowing guidance intervention, although most patients seemed to benefit, as indicated by reduced EAT-10 scores. Larger case-control studies are needed to establish the true effect of the intervention. Efficacy studies of therapeutic interventions are inherently challenging due to confounding factors, small subpopulations, and unstandardized treatment protocols. The functional dysphagia group was diverse, and factors such as symptom duration, additional functional symptoms, or neuropsychiatric comorbidities were not considered. The one-month follow-up was short, and a longer follow-up might have revealed more sustained effects. Nonetheless, the study demonstrated that even a brief intervention could yield benefits, particularly in reducing fear and anxiety through validation and education. Finally, globus patients were included in the study, though they are not considered true dysphagia cases.

6.9 Future perspectives

We introduced rapid and straightforward methods for evaluating and potentially treating dysphagia. The EAT-10 questionnaire, including its Finnish version, serves as an efficient and accessible tool for expanding patient history. It is particularly useful when completed prior to an appointment, providing a quick insight into swallowing problems. The water swallow test (WST) is quick to administer, using universally available tools (a glass and water), making it valuable for dysphagia screening. Although multiple versions of the WST exist, to our knowledge, Study II was the first to investigate individual test parameters, such as cough observation and swallow count (average bolus size), as the most useful indicators. This finding is especially relevant in high-volume clinical settings.

While various instrumental assessments for dysphagia are available, it is neither practical nor cost-effective to subject every patient to all diagnostic examinations. Moreover, unnecessary testing may worsen symptoms by promoting illness behaviour or inducing iatrogenic symptoms, especially in cases of functional dysphagia. The initial evaluation of a patient with dysphagia should allow sufficient time for a detailed history and, ideally, incorporate FEES with swallowing guidance to direct further diagnostics as appropriate. In many cases, this may be the only intervention required.

EAT-10 has been widely used as a screening tool, although it was not specifically designed for this purpose. A psychometric evaluation of the Finnish version of EAT-10 would be valuable. While the water swallow test (WST) is more effective for screening, a simplified version requires further investigation. Despite the crucial role of swallowing screening and evaluation, they are often overlooked in many settings. Greater collaboration and education in this area are essential. Dysphagia management spans multiple medical disciplines, highlighting the need for interdisciplinary dialogue and cooperation. At our hospital, we established a multidisciplinary dysphagia meeting in 2022 to enhance understanding and foster collaboration. Additionally, interdisciplinary master's programs in deglutology have been developed, such as the Master's Degree in Deglutology in Leuven, Belgium, and the Master's and Postgraduate Diploma in Swallowing Disorders in Barcelona, Spain.

Standardization is important in dysphagia assessment. As briefly highlighted in Study II, bolus size plays a critical role in evaluation. A 20 ml bolus should be included in the VFS protocol, as it represents a large yet normal swallow challenge. Future research should determine the optimal bolus sizes and consistencies for VFS while adhering to ALARA principles to minimize unnecessary radiation exposure. Objective measurements in VFS ratings could be valuable, though their clinical utility requires further investigation due to the time-consuming nature of these assessments in daily practice. Automated methods, such as artificial intelligence or

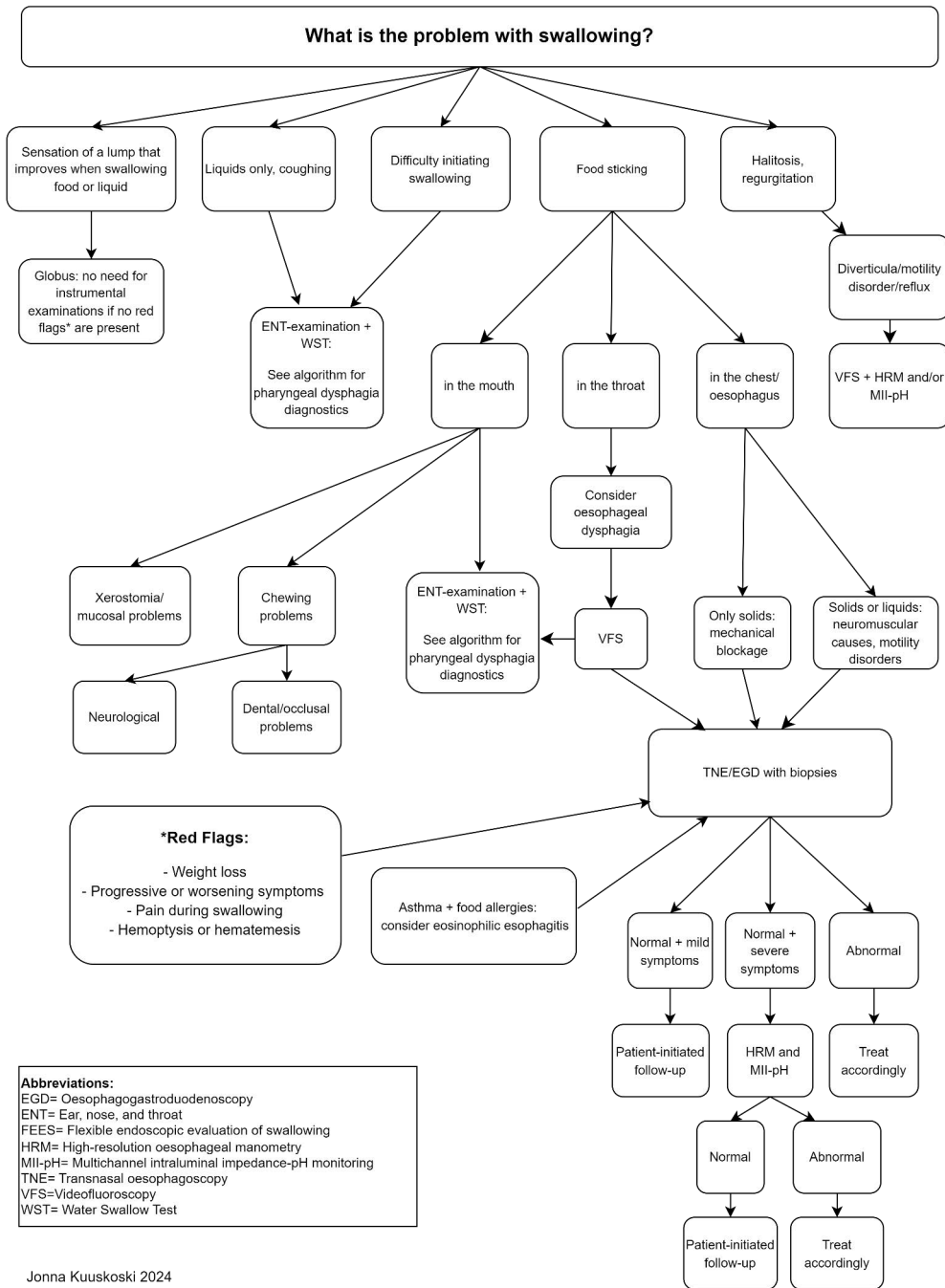
deep learning for detecting aspiration, could enhance diagnostic accuracy and warrant further exploration.

Pharyngeal manometry has gained popularity in recent years. While it is not routinely used in our hospital, it could offer valuable insights into swallowing disorders and assist in treatment planning.

Based on these studies and our clinical experience, we developed diagnostic algorithms to aid clinical decision-making, considering dysphagia symptoms and the presence of findings from ENT examinations or the WST (Figure 10 and 11). Assessing dysphagia patients in the appropriate setting helps prevent resource inefficiency and delays in diagnosis.

Managing functional dysphagia can be challenging, but recent advances in understanding brain-body interactions and tools to reinforce beneficial behaviours and reduce bodily distress show promise. FEES is particularly helpful in such cases. There is a need for improved national guidelines, as recently emphasized by Liira et al. in *Suomen Lääkärilehti* (Finnish Medical Journal) (2024). Moreover, incorporating a ‘functional insight’ into all treatments is beneficial. Illness behaviours can create a vicious cycle, and excessive testing can lead to iatrogenic symptoms by reinforcing unhelpful illness perceptions and triggering a nocebo effect. In conclusion, the importance of a strong doctor-patient-relationship cannot be overstated, as expressed in a famous quote attributed to Malcolm X (1925-1965): “When I is replaced by We, even illness becomes wellness”.

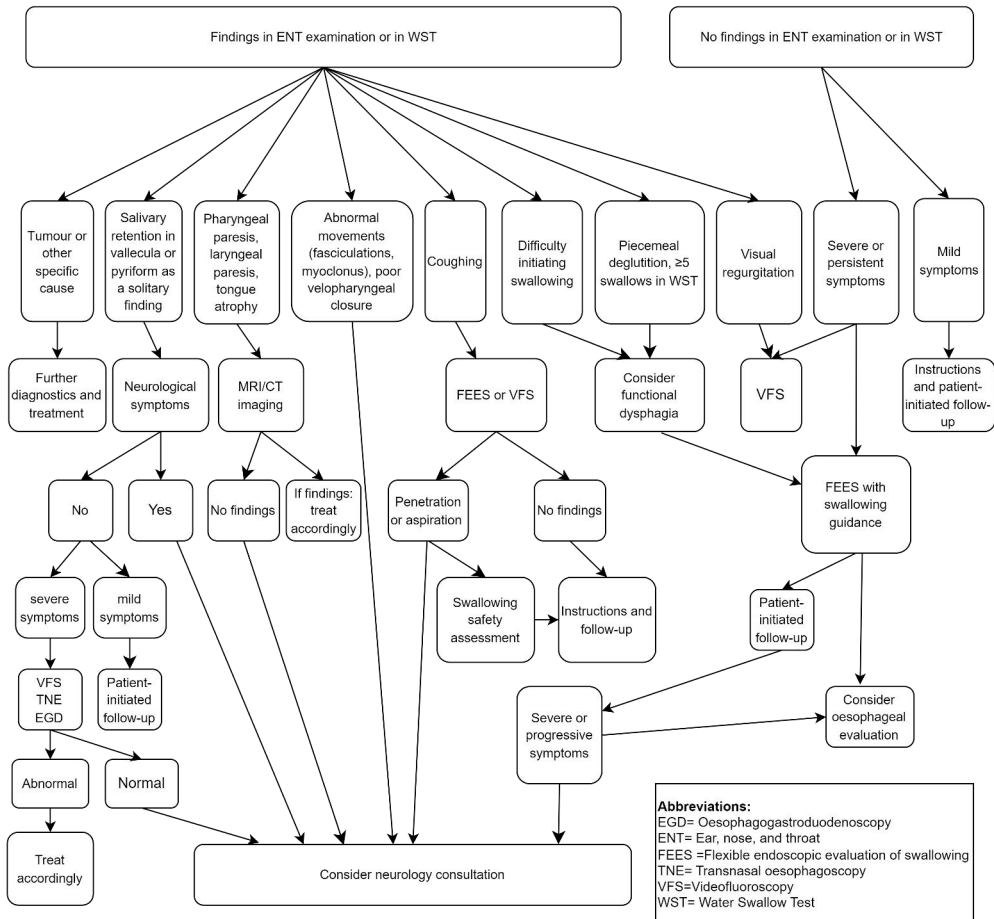
Symptom-based diagnostic algorithm for swallowing difficulties



Jonna Kuuskoski 2024

Figure 10. Symptom-based diagnostic algorithm for swallowing difficulties. Image: Kuuskoski J.

Algorithm for pharyngeal dysphagia diagnostics



Jonna Kuuskoski 2024

Figure 11. Algorithm for pharyngeal dysphagia diagnostics. Image: Kuuskoski J.

7 Conclusions

1. The Finnish version of EAT-10 is a valid and reliable tool for assessing swallowing difficulties and is suitable for follow-up evaluations. Additionally, EAT-10 can help identify patients at risk for penetration and aspiration.
2. The WST outperformed the EAT-10 in identifying patients who should be referred for VFS. In the WST, coughing and average drinking bolus size were key predictors of VFS results, while swallowing speed appeared less relevant. A 20 ml bolus was more sensitive in detecting penetration or aspiration in VFS than a 10 ml bolus.
3. Subjective evaluation of VFS showed moderate to strong agreement on pharyngeal findings, particularly in identifying pharyngeal residue and penetration/aspiration, which are critical for assessing swallowing safety and efficiency. Objective spatial and temporal measurements demonstrated moderate to good inter-observer consistency, suggesting their potential to enhance VFS diagnostic reliability. However, further research is needed to fully establish the clinical value of these objective measurements.
4. Dysphagia significantly reduces patients' HRQoL compared to the general population. A brief, one-time FEES session, combined with swallowing guidance and video feedback, may be particularly beneficial for patients with functional dysphagia.

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Turku, March 2025,

A handwritten signature in black ink, appearing to read 'Jonna', with a long, sweeping underline that extends to the right and then loops back down.

Jonna Kuuskoski

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Appendices

Appendix 1a. Videofluoroscopy Finding Form in Finnish (Study II, III)

Videofluoroskopialöydösten arviointilomake

Päivämäärä :

Potilaan nimi:

Potilaan henkilötunnus:

Arvioija :

		Nestemäinen (IDDSI 0)		Sakeutettu (IDDSI 3)		Kiinteä (IDDSI 5–7)	
Suuvaiheen löydökset	Huulion sulku	normaali	poikkeava	normaali	poikkeava	normaali	poikkeava
	Kielen liike	normaali	poikkeava	normaali	poikkeava	normaali	poikkeava
	Ennenaikainen nieluun valahtaminen	ei	kyllä	ei	kyllä	ei	kyllä
	Suuontelon residuaali	ei	kyllä	ei	kyllä	ei	kyllä
Nieluvaiheen löydökset	Nielemisen käynnistyminen	normaali	viivästynyt	normaali	viivästynyt	normaali	viivästynyt
	Nenänielun sulkeutuminen	normaali	poikkeava	normaali	poikkeava	normaali	poikkeava
	Epiglottiksen retrofleksio	normaali	poikkeava	normaali	poikkeava	normaali	poikkeava
	Kurkunpään nousu	normaali	poikkeava	normaali	poikkeava	normaali	poikkeava
	Vallekulariduaali	ei	kyllä	ei	kyllä	ei	kyllä
	Fossa piriformis residuaali	ei	kyllä	ei	kyllä	ei	kyllä
	Penetraatio/aspiraatio	ei	kyllä	ei	kyllä	ei	kyllä
Ruokatorvivaikkeen löydökset	Yläsulkijan toiminta	normaali	poikkeava	normaali	poikkeava	normaali	poikkeava
	Ruokatorven peristaltiikka	normaali	poikkeava	normaali	poikkeava	normaali	poikkeava
	Ruokatorven obstruktio	ei	kyllä	ei	kyllä	ei	kyllä
	Alasulkijan toiminta	normaali	poikkeava	normaali	poikkeava	normaali	poikkeava

PAS-pisteet			
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Muuta erityistä (hiatushernia, Zenkerin divertikkeli tms):

Penetration-Aspiration Scale

Score	Classification	Description
1	None	No entry of material into the larynx or trachea
2	Penetration	Entry of material into the larynx with clearing
3	Penetration	Entry of material into the larynx without clearing
4	Penetration	Material contacts the true vocal folds with clearing
5	Penetration	Material contacts the true vocal folds without clearing the larynx
6	Aspiration	Material enters the trachea and is spontaneously cleared into the larynx or pharynx
7	Aspiration	Material enters the trachea and is not cleared following attempts
8	Aspiration	Material enters the trachea with no attempt to clear

(Rosenbek et al. 1996)

Jonna Kuuskoski 2024

Appendix 1b. Videofluoroscopy Finding Form in English

Videofluoroscopy Finding Form

Date :

Patient's name :

Patient's ID :

Evaluator :

		Liquid (IDDSI 0)		Thickened (IDDSI 3)		Solid (IDDSI 5–7)	
		normal	abnormal	normal	abnormal	normal	abnormal
Oral Findings	Lip closure	normal	abnormal	normal	abnormal	normal	abnormal
	Tongue movement	normal	abnormal	normal	abnormal	normal	abnormal
	Premature pharyngeal spillage	absent	present	absent	present	absent	present
	Oral residue	absent	present	absent	present	absent	present
Pharyngeal Findings	Swallow onset	normal	delayed	normal	delayed	normal	delayed
	Velopharyngeal closure	normal	abnormal	normal	abnormal	normal	abnormal
	Epiglottal retroflexion	normal	abnormal	normal	abnormal	normal	abnormal
	Laryngeal elevation	normal	abnormal	normal	abnormal	normal	abnormal
	Vallecular residues	absent	present	absent	present	absent	present
	Pyramidal sinus residues	absent	present	absent	present	absent	present
	Penetration/aspiration	absent	present	absent	present	absent	present
	Oesophageal Findings	UES opening	normal	abnormal	normal	abnormal	normal
Oesophageal peristalsis		normal	abnormal	normal	abnormal	normal	abnormal
Oesophageal stasis		absent	present	absent	present	absent	present
LES function		normal	abnormal	normal	abnormal	normal	abnormal

PAS-score			
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Other specific condition (such as hiatus hernia or Zenker's diverticulum):

Penetration-Aspiration Scale

Score	Classification	Description
1	None	No entry of material into the larynx or trachea
2	Penetration	Entry of material into the larynx with clearing
3	Penetration	Entry of material into the larynx without clearing
4	Penetration	Material contacts the true vocal folds with clearing
5	Penetration	Material contacts the true vocal folds without clearing the larynx
6	Aspiration	Material enters the trachea and is spontaneously cleared into the larynx or pharynx
7	Aspiration	Material enters the trachea and is not cleared following attempts
8	Aspiration	Material enters the trachea with no attempt to clear

(Rosenbek et al. 1996)

Jonna Kuuskoski 2024

Appendix 2. 15D Instrument (Study IV)

QUALITY OF LIFE QUESTIONNAIRE (15D©)

Please read through all the alternative responses to each question before placing a cross (x) against the alternative which best describes **your present health status**. Continue through all 15 questions in this manner, giving only **one** answer to each.

QUESTION 1. MOBILITY

- 1 () I am able to walk normally (without difficulty) indoors, outdoors and on stairs.
- 2 () I am able to walk without difficulty indoors, but outdoors and/or on stairs I have slight difficulties.
- 3 () I am able to walk without help indoors (with or without an appliance), but outdoors and/or on stairs only with considerable difficulty or with help from others.
- 4 () I am able to walk indoors only with help from others.
- 5 () I am completely bed-ridden and unable to move about.

QUESTION 2. VISION

- 1 () I see normally, i.e. I can read newspapers and TV text without difficulty (with or without glasses).
- 2 () I can read papers and/or TV text with slight difficulty (with or without glasses).
- 3 () I can read papers and/or TV text with considerable difficulty (with or without glasses).
- 4 () I cannot read papers or TV text either with glasses or without, but I can see enough to walk about without guidance.
- 5 () I cannot see enough to walk about without a guide, i.e. I am almost or completely blind.

QUESTION 3. HEARING

- 1 () I can hear normally, i.e. normal speech (with or without a hearing aid).
- 2 () I hear normal speech with a little difficulty.
- 3 () I hear normal speech with considerable difficulty; in conversation I need voices to be louder than normal.
- 4 () I hear even loud voices poorly; I am almost deaf.
- 5 () I am completely deaf.

QUESTION 4. BREATHING

- 1 () I am able to breathe normally, i.e. with no shortness of breath or other breathing difficulty.
- 2 () I have shortness of breath during heavy work or sports, or when walking briskly on flat ground or slightly uphill.
- 3 () I have shortness of breath when walking on flat ground at the same speed as others my age.
- 4 () I get shortness of breath even after light activity, e.g. washing or dressing myself.
- 5 () I have breathing difficulties almost all the time, even when resting.

QUESTION 5. SLEEPING

- 1 () I am able to sleep normally, i.e. I have no problems with sleeping.
- 2 () I have slight problems with sleeping, e.g. difficulty in falling asleep, or sometimes waking at night.
- 3 () I have moderate problems with sleeping, e.g. disturbed sleep, or feeling I have not slept enough.
- 4 () I have great problems with sleeping, e.g. having to use sleeping pills often or routinely, or usually waking at night and/or too early in the morning.
- 5 () I suffer severe sleeplessness, e.g. sleep is almost impossible even with full use of sleeping pills, or staying awake most of the night.

QUESTION 6. EATING

- 1 () I am able to eat normally, i.e. with no help from others.
- 2 () I am able to eat by myself with minor difficulty (e.g. slowly, clumsily, shakily, or with special appliances).
- 3 () I need some help from another person in eating.
- 4 () I am unable to eat by myself at all, so I must be fed by another person.
- 5 () I am unable to eat at all, so I am fed either by tube or intravenously.

QUESTION 7. SPEECH

- 1 () I am able to speak normally, i.e. clearly, audibly and fluently.
- 2 () I have slight speech difficulties, e.g. occasional fumbling for words, mumbling, or changes of pitch.
- 3 () I can make myself understood, but my speech is e.g. disjointed, faltering, stuttering or stammering.
- 4 () Most people have great difficulty understanding my speech.
- 5 () I can only make myself understood by gestures.

QUESTION 8. EXCRETION

- 1 () My bladder and bowel work normally and without problems.
- 2 () I have slight problems with my bladder and/or bowel function, e.g. difficulties with urination, or loose or hard bowels.
- 3 () I have marked problems with my bladder and/or bowel function, e.g. occasional 'accidents', or severe constipation or diarrhea.
- 4 () I have serious problems with my bladder and/or bowel function, e.g. routine 'accidents', or need of catheterization or enemas.
- 5 () I have no control over my bladder and/or bowel function.

QUESTION 9. USUAL ACTIVITIES

- 1 () I am able to perform my usual activities (e.g. employment, studying, housework, free-time activities) without difficulty.
- 2 () I am able to perform my usual activities slightly less effectively or with minor difficulty.
- 3 () I am able to perform my usual activities much less effectively, with considerable difficulty, or not completely.
- 4 () I can only manage a small proportion of my previously usual activities.
- 5 () I am unable to manage any of my previously usual activities.

QUESTION 10. MENTAL FUNCTION

- 1 () I am able to think clearly and logically, and my memory functions well
- 2 () I have slight difficulties in thinking clearly and logically, or my memory sometimes fails me.
- 3 () I have marked difficulties in thinking clearly and logically, or my memory is somewhat impaired.
- 4 () I have great difficulties in thinking clearly and logically, or my memory is seriously impaired.
- 5 () I am permanently confused and disoriented in place and time.

QUESTION 11. DISCOMFORT AND SYMPTOMS

- 1 () I have no physical discomfort or symptoms, e.g. pain, ache, nausea, itching etc.
- 2 () I have mild physical discomfort or symptoms, e.g. pain, ache, nausea, itching etc.
- 3 () I have marked physical discomfort or symptoms, e.g. pain, ache, nausea, itching etc.
- 4 () I have severe physical discomfort or symptoms, e.g. pain, ache, nausea, itching etc.
- 5 () I have unbearable physical discomfort or symptoms, e.g. pain, ache, nausea, itching etc.

QUESTION 12. DEPRESSION

- 1 () I do not feel at all sad, melancholic or depressed.
- 2 () I feel slightly sad, melancholic or depressed.
- 3 () I feel moderately sad, melancholic or depressed.
- 4 () I feel very sad, melancholic or depressed.
- 5 () I feel extremely sad, melancholic or depressed.

QUESTION 13. DISTRESS

- 1 () I do not feel at all anxious, stressed or nervous.
- 2 () I feel slightly anxious, stressed or nervous.
- 3 () I feel moderately anxious, stressed or nervous.
- 4 () I feel very anxious, stressed or nervous.
- 5 () I feel extremely anxious, stressed or nervous.

QUESTION 14. VITALITY

- 1 () I feel healthy and energetic.
- 2 () I feel slightly weary, tired or feeble.
- 3 () I feel moderately weary, tired or feeble.
- 4 () I feel very weary, tired or feeble, almost exhausted.
- 5 () I feel extremely weary, tired or feeble, totally exhausted.

QUESTION 15. SEXUAL ACTIVITY

- 1 () My state of health has no adverse effect on my sexual activity.
- 2 () My state of health has a slight effect on my sexual activity.
- 3 () My state of health has a considerable effect on my sexual activity.
- 4 () My state of health makes sexual activity almost impossible.
- 5 () My state of health makes sexual activity impossible.



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