

Predictability of Oral and Laryngopharyngeal Function for Aspiration and Limitation of Oral Intake in Patients After Surgery for Head and Neck Cancer

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Abstract. *Swallowing disorders are common in patients after surgery for head and neck cancer. The clinical assessment of oral and laryngopharyngeal abilities is widely used as a dysphagia assessment tool in this patient group, despite a lack of research. The goal of this study was to assess the predictability of clinical parameters for aspiration and limitation of oral intake. A swallowing disorder with the need for further intervention was identified by fiberoptic endoscopic evaluation of swallowing (FEES) in 65%, with aspiration in 49%, silently in 21%, and limited oral intake with tube dependency in 56% of studied patients. Four clinical parameters (dysglossia, wet voice, tongue motility, and tongue strength) correlated significantly with aspiration and limitation of oral intake. However, none of these clinical parameters was able to predict one of our two reference criteria, due to low positive likelihood ratios, mostly less than two. Clinical assessment is therefore inappropriate for early detection of swallowing disorders in such patients.*

Swallowing disorders are still a common sequelae of tumor resection in patients with head and neck cancer (HNC) (1), despite improved modern resection and reconstruction procedures (2-5). The prevalence rate is reported to be up to 88% (6-8) depending on localization, tumor size, and chosen treatment. Due to the frequent occurrence of post-surgical biomechanical dysfunctions, the examination of the

swallowing-related oral and laryngopharyngeal abilities in this patient group is widely used as a dysphagia assessment tool, irrespective of the lack of research concerning its clinical utility.

Today, research is largely focused on the examination of non-swallowing oral and laryngeal functions as clinical parameters due to the possibility of predicting swallowing problems, predominantly in patients after stroke. The most frequently reported parameters are dysarthria (9-15), wet voice (10, 11, 12, 16), limited tongue motility (17, 18) and strength (19, 20), abnormal volitional cough (10, 11, 12, 21-23), and absent gag reflex (10-12, 22, 24, 25) as more or less sensitive signs of aspiration, are the most critical aspect of swallowing disorders in patients after stroke. Limitation of oral intake as a typical result of impaired bolus propulsion is not rare post-surgically in patients with HNC as a sign of severe oropharyngeal dysphagia even without signs of aspiration. It is of interest whether these clinical parameters, together with limitations in mouth opening, often occurring in patients with HNC (26), can be predictive of swallowing disorders with the need for further intervention in patients after surgery for HNC.

Therefore, the goal of the present study was to identify in such patients: (a) the predictability of the clinical parameters dysglossia, wet voice, abnormal volitional cough, reduced mouth opening, limited tongue motility, limited tongue strength, and gag reflex for the reference criteria aspiration and limitation of oral intake defined by fiberoptic endoscopic evaluation of swallowing (FEES); and (b) whether the combination of significantly correlating parameters enhances the predictability of these disorders.

Patients and Methods

Patients. Between November 2010 and December 2012, 98 patients were recruited for the presented prospective study after surgery for HNC. Inclusion criteria were defined as Union internationale contre

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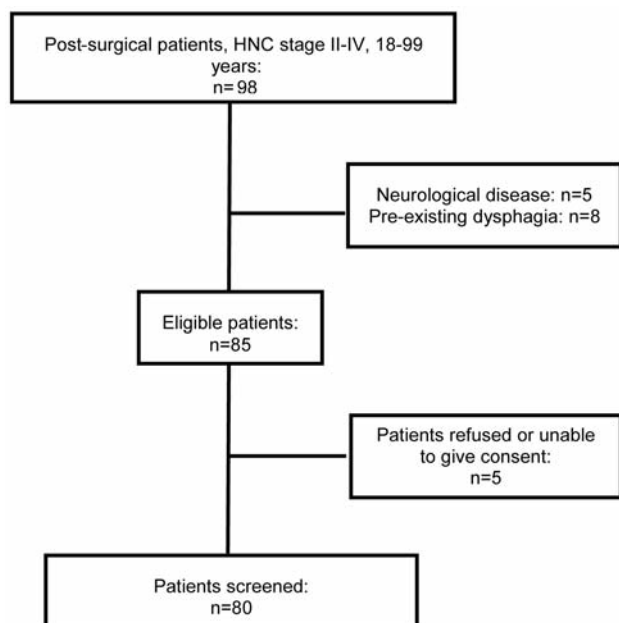


Figure 1. Study inclusion flow diagram.

le cancer (UICC) stage II–IV, age between 18 and 99 years, and written informed consent. Exclusion criteria were neurological diseases and pre-existing oropharyngeal dysphagia. Out of the 98 patients, five were excluded due to neurological diseases, eight due to pre-existing oropharyngeal dysphagia, and five due to refused consent (Figure 1).

A total of 80 patients were thus included in our study, predominantly men (58 male, 22 female), with a mean age of 60.96 years (SD=12.93 years; range=18.92 to 87.75 years). Refer to Table I for patient characteristics.

The study was approved by the Institutional Review Board of the University Hospital Frankfurt/Main, Germany (approval # 240/10).

Procedure. After tumor resection and surgeon’s approval for oral intake, all included patients firstly underwent clinical swallowing assessment performed by one of two speech and language pathologists (SLP), both with over five years’ experience in dysphagia evaluation and treatment. As a reference standard, fiberoptic endoscopic evaluation of swallowing (FEES, Langmore standard) (27) was performed with a time frame of one hour after the clinical swallowing assessment. The examiner and rater of the FEES was a phoniatrician with over 10 years’ FEES experience, blinded to information regarding the results of the two SLPs.

Clinical swallowing assessment. The clinical swallowing assessment, including dysglossia, wet voice, volitional cough, range of mouth opening, tongue motility, tongue strength, and gag reflex, was standardized and binarily scored with a pass/fail judgment (see Table II). Both SLPs were trained in administering and interpreting the seven clinical parameters on five healthy subjects and 20 patients with HNC who were not included in the study to optimize test reliability. Confirming inter- and intra-rater reliability tests was performed on 24

Table I. Patients’ characteristics.

	n	%
Age (years)		
≤40	4	5.0
41-60	34	42.4
>60	42	52.5
Gender		
Male	58	72.5
Female	22	27.5
Tumour stage		
II	23	28.8
III	9	11.3
IV	48	60.0
Tumour site		
Cavitas oris	30	37.5
Oropharynx	34	42.5
Hypopharynx/larynx	16	20.0

additional patients with HNC. The entire clinical swallowing assessment was administered and scored in less than 10 minutes.

Reliability. The overall intra-rater reliability (Cohen’s $\kappa=1.00$, $p<0.001$) and the overall inter-rater reliability (Cohen’s $\kappa=0.98$; $p<0.001$) were both excellent.

FEES. The FEES examinations were performed by the first author Christiane Hey according to the FEES protocol by Langmore *et al.* (27). The recordings were taken with the ENT video endoscopy system EndoStrob-DX (Xion medical GmbH, Berlin, Germany) (video system: PAL; output: S-Video, DVI-I, VGA IEEE/1394 (DV); input DVI-I, S-Video; 3 lux; sensor: CCD matrix with micro lenses and mosaic filter, 1/3” 752 (h) x 582 (v) pixels; digital interfaces: IEEE/1394 FireWire DV; light source: power 50 W; color temperature 5.700 K; camera head with integrated microphone, videoadapter: focal length 22 mm; clip coupling) and the transnasal flexible endoscope 11101 RP2 (Karl Storz GmbH, Tuttlingen, Germany).

The examination was initiated with 2 ml water and followed accordingly with 5, 10, and 20 ml. In addition, pure and solid consistencies with progressive volume were tested. If a patient aspirated, without the possibility of improving swallowing ability by therapeutic maneuvers, the FEES examination was discontinued.

The level of aspiration was scored by the eight-point penetration-aspiration scale (PAS) by Rosenbek *et al.* (28), the level of oral intake by the seven-point functional oral intake scale (FOIS) (29). Dysphagia with the need for further intervention was defined by a PAS ≥ 4 (4=material enters the airway, contacts the vocal folds, and is ejected from the airway), or FOIS ≤ 4 (4=total oral diet of a single consistency), aspiration by a PAS ≥ 6 (6=material enters the airway, passes below the vocal folds, and is ejected into the larynx or out of the airway), and therapy-relevant limitation of oral intake by FOIS ≥ 4 .

FEES reliability. Assessments were rated by the first author Christiane Hey, who also re-rated 20% of the digital clips at least two months after the initial examination in order to assess the intra-rater reliability. Ten percent of the recordings were rated by the second person with experience in FEES, who was blinded to the

Table II. Examination of the clinical parameters.

Parameter	Method
1. Dysglossia:	Evaluation during initial dialog
2. Wet voice:	Evaluation during initial dialog
3. Volitional cough:	Command to cough
4. Mouth opening:	Command to open mouth as wide as possible
5. Tongue motility:	Tasks: Protraction Lateral movements Vertical movements in median position Circular tongue movements on the lips Articulation: tututututut, kukukukukuk
6. Tongue strength:	Task: tongue pressed against the cheek with resistance of two fingers of the examiner
7. Gag reflex:	Triggered by the touch of the right/left palatal arch and posterior wall of the pharynx

patients' details, to assess the inter-rater reliability. The overall intra-rater reliability (Cohen's $\kappa=0.89$, $p<0.001$) and the overall inter-rater reliability (Cohen's $\kappa=0.92$, $p<0.001$) were both excellent.

Statistical analyses. The prevalence of dysphagia as well as both reference criteria aspiration and limitation of oral intake in our study population were determined by descriptive statistics.

Direction and strength of relationships with both reference criteria were tested using Pearson's correlation.

An analysis of variance (ANOVA) was calculated to test the effects of tumor site and stage.

For the significantly correlating clinical parameters, the accuracy was determined by sensitivity, specificity, and the positive likelihood ratio (LR).

All statistical analyses were performed using SPSS (Version 20, International Business Machines Corp., Armonk, New York, USA).

Results

FEES results. A swallowing disorder with the need for further intervention was identified by FEES in 65.0% (52/80), with aspiration in 48.8% (39/80), silently in 21.3% (17/80), and limitation of oral intake with tube dependency in 56.3% (45/80) of all patients with HNC. A level of 4 in the FOIS did not occur in any of the patients.

The more advanced the tumor stage, the higher the rate of aspiration and tube dependency. Refer to Table III for prevalence, as well as tumor stage and site-related details.

Regarding the tumor site, the patients with oropharyngeal carcinoma presented therapy-relevant dysphagia in 73.5% (25/34) aspiration in 61.8% (21/34), and tube dependency in 67.7% (23/34) of cases. However, as revealed by ANOVA, the tumor site had no effect on the two reference criteria ($p>0.4$; $\eta_p^2<0.03$), whereas tumor stage influenced both aspiration ($p=0.005$; $\eta_p^2=0.138$) and limitation of oral intake ($p=0.010$; $\eta_p^2=0.122$).

Correlation of the clinical parameters with aspiration, oral intake, and therapy-relevant dysphagia. Three out of seven

Table III. Fiberoptic endoscopic evaluation of swallowing (FEES) results regarding dysphagia (*defined as penetration-aspiration scale (PAS) ≥ 4 or functional oral intake scale (FOIS) ≤ 4), aspiration, and limitation of oral intake.

Patient characteristic	Dysphagia*		Aspiration (PAS ≥ 6)		Limitation of oral intake (FOIS ≤ 4)	
	n	n (%)	n (%)	n (%)	n (%)	n (%)
Tumour stage						
II	23	9 (39.1)	5 (12.8)		6 (26.1)	
III	9	5 (55.6)	3 (33.3)		4 (44.4)	
IV	48	38 (79.2)	31 (79.4)		35 (72.9)	
Tumour site						
Cavitas oris	30	19 (63.3)	11 (36.7)		16 (53.3)	
Oropharynx	34	25 (73.5)	21 (61.8)		23 (67.7)	
Hypopharynx/larynx	16	8 (50.0)	7 (43.8)		6 (37.5)	
Total	80	52 (65.0)	39 (48.8)		45 (56.3)	

clinical parameters, namely mouth opening, volitional cough, and gag reflex, showed no noteworthy correlation with either reference criterion ($r\leq 0.2$; $p>0.05$) and were thus considered negligible (see Table IV).

The remaining four parameters, namely dysglossia, wet voice, tongue motility, and tongue strength, were identified to be significantly related to limitation of oral intake and, except for dysglossia, with aspiration (Table IV).

The raw data, sensitivity, specificity, and the positive LR are listed for these four clinical parameters and their combinations in Table V.

The highest sensitivity for aspiration and limitation of oral intake was identified for tongue strength (aspiration=79.49%, limitation of oral intake=75.56%) and tongue motility (aspiration=74.36%, limitation of oral intake=71.11%) but

Table IV. Pearson's correlation of all clinical parameters with aspiration and limitation of oral intake.

	Aspiration (PAS ≥6) (r)	Limitation of oral intake (FOIS ≤4) (r)
Dysglossia	0.20	0.37**
Wet voice	0.38**	0.45**
Volitional cough	0.01	0.09
Mouth opening	0.11	0.20
Tongue motility	0.28*	0.35**
Tongue strength	0.28*	0.33**
Gag reflex	0.13	0.12

df=79 for all correlations; *p<0.05; **p<0.01.

both with low specificity (with values from 51.22% to 57.14%) and therefore with a low positive likelihood ratio. The highest specificity was detected for wet voice (aspiration=90.24%, limitation of oral intake=94.29%) with a good likelihood ratio (aspiration 4.21, limitation of oral intake 7), however with low sensitivity (aspiration=41.02%, limitation of oral intake=40%). The lowest accuracy parameters were presented by dysglossia, especially for aspiration, with a positive LR of 1.23.

Analyzed combinations of two or more failed clinical parameters, and three or more failed clinical parameters did not improve the diagnostic accuracy significantly (Table V).

Discussion

The high prevalence of aspiration (49%), limitation of oral intake (56%), and swallowing disorder with need for further intervention (65%) in our study underlines that post-surgically patients with HNC have to be defined as a high-risk group for developing dysphagia and aspiration. Noteworthy is the rate of silent aspiration, over 20% of our patients, which is as high as that reported normally for patients with HNC following (chemo-)radiation (30-32). While tumor site did not influence the prevalence rate, increasing tumor stage extended the risk of aspiration and limitation of oral intake. This corresponds to the results of previous research showing that the larger the tumor size and resection, the greater the signs of dysphagia (30, 33-36).

The goal of our study was to examine the predictability of seven clinical parameters of non-swallowing oral and laryngeal functions for aspiration and limitation of oral intake in patients after surgery for HNC. To enhance the reliability of testing, we standardized the examination and simplified interpretation with binary pass/fail decisions. We also trained two SLPs in the administration and judging of the clinical assessment before commencement of the study.

As a result, the intra- and inter-rated reliability was excellent in our study when compared to studies in which prior training was not applied (23), which underscores the necessity for standardization and training in order to achieve unified and valid examinations of clinical parameters as recommended in several articles (17, 18, 37).

In our study population, which is representative insofar as it matches the prevalence rate of German patients with HNC (38), four clinical parameters, namely dysglossia, wet voice, tongue motility, and tongue strength, correlated significantly with the FEES-detected signs of dysphagia; the three others, namely reduced mouth-opening, abnormal volitional cough, and absent gag reflex, did not. The two latter are also discussed controversially for patients after stroke, and categorically denied among others (23, 39, 40-42).

In our study, tongue motility and tongue strength presented the highest sensitivity, with values from 71% to 80% in all target conditions, therefore these two parameters could be interpreted as possible predictors. However, ruling a disease for subsequent management or not, has to result in a comparison of pre- and post-test probability instead of considering sensitivity and specificity in isolation as is widespreadly done (43). The LR is a statistic quality criterion that is more useful clinically than other statistical criteria (44). It converts the pre-test into post-test probability by combining sensitivity and specificity. In contrast to predictive values it is prevalence-independent and indicates how more or less probable patients with aspiration or limitation of oral intake are to have a positive test result within our clinical parameters than patients without the target condition. A positive LR value of 1 demonstrates that the probability of having a specific test result is equal for patients both with and without the target condition, which points out that such a test result is not able to differentiate between patients with and without the target condition. LR of 1 to 2 alters probability to a small and rarely important degree; LR of 2 to 5 generates small changes in probability; LR of 5 to 10 generates moderate shifts in pre-test to post-test probability (45). Given this, none of our four significantly correlating clinical parameters was able to predict aspiration or limitation of oral intake sufficiently, with values of LR mostly being less than two. Even if wet voice demonstrates a remarkably high specificity (90% to 94%) and good LR (4 to 7), because specificity influences the positive LR (46), wet voice does not reflect a valid predictor due to its low sensitivity.

Combining reliable clinical parameters is proposed in order to enhance validity over single items for the better predictability of aspiration in patients after stroke (10-12, 17, 23). Daniels *et al.* revealed that the presence of two out of six clinical parameters (dysarthria, dysphonia, abnormal volitional cough, abnormal gag reflex, cough or throat clearing and voice change after swallow) validly predicts aspiration in patients

Table V. Diagnostic accuracy measures for the four identified clinical parameters for aspiration and limitation of oral intake.

Item	Aspiration				Limitation of oral intake			
	Results (tp/fp/fn/tn)	Sensitivity % (95% CI)	Specificity % (95% CI)	LR (95% CI)	Results (tp/fp/fn/tn)	Sensitivity % (95% CI)	Specificity % (95% CI)	LR (95% CI)
Dysglossia	21/18/18/23	53.85 (37.18-69.91)	56.1 (39.75-71.53)	1.23 (0.78-1.93)	28/11/17/24	62.22 (46.54-76.23)	68.57 (50.71-83.15)	1.98 (1.15-3.40)
Wet voice	16/4/23/37	41.02 (25.57-57.90)	90.24 (76.87-97.28)	4.21 (1.54-11.48)	18/2/27/33	40.00 (25.70-55.67)	94.29 (80.84-99.3)	7.00 (1.74-28.17)
Tongue motility	29/18/10/23	74.36 (57.87-86.96)	56.10 (39.75-71.53)	1.69 (1.14-2.51)	32/15/13/20	71.11 (55.69-83.63)	57.14 (39.35-73.68)	1.66 (1.08-2.54)
Tongue strength	31/20/8/21	79.49 (63.54-90.7)	51.22 (35.13-67.12)	1.63 (1.15-2.32)	34/17/11/18	75.56 (60.46-87.12)	51.43 (33.99-68.62)	1.56 (1.07-2.27)
Combination 1	22/19/9/30	70.97 (51.96-85.78)	61.22 (46.24-74.80)	1.83 (1.21-2.78)	21/14/10/35	67.74 (48.63-83.32)	71.43 (56.74-83.42)	2.37 (1.43-3.93)
Combination 2	28/13/16/23	63.64 (47.77-77.59)	63.89 (46.22-79.18)	1.76 (1.08-2.87)	26/9/18/27	59.09 (43.25-73.66)	75.00 (57.8-87.88)	2.36 (1.28-4.38)

tp: True-positive; fp: false-positive; fn: false-negative; tn: true-negative; LR: positive likelihood ratio; CI: confidence interval. Combination 1: ≥ 2 failed clinical parameters; combination 2: ≥ 3 failed clinical parameters.

after stroke (Sensitivity=69.6%, Specificity=84.4%, LR=4.46) (11). McCullough *et al.* detected a better validity with the presence of four rather than two of the same clinical parameters (Sensitivity=77.8%, Specificity=71.9%, LR=2.76) (23). Leder *et al.*, however, denied that these six clinical parameters are able to predict aspiration in patients after stroke (Sensitivity=86.4%, Specificity=29.6%, LR=1.23) (40). In contrast to the former studies, Leder *et al.* used FEES instead of the Videofluoroscopic Swallowing Study (VFSS) as the reference gold standard. In our study, the combination of the four correlating parameters (dysglossia, wet voice, tongue motility, and tongue strength), as a combination of two or more failed clinical parameters (aspiration: Sensitivity=71.0%, Specificity=61.2%, LR=1.83; limitation of oral intake: Sensitivity=67.7%, Specificity=71.4%, LR=2.37), and as a combination of three or more failed clinical parameters (aspiration: Sensitivity=63.6%, Specificity=63.9%, LR=1.76; limitation of oral intake: Sensitivity=59.1%, Specificity=75.0%, LR=2.36), did in fact improve the test properties when compared to the validity of each single parameter but was still not convincing.

However, beside the obvious fact that these four clinical parameters are really not able to predict aspiration and limitation of oral intake, a possible reason for this result, compared to the studies by Daniels *et al.* and McCullough *et al.*, is that we had only four rather than six clinical parameters to combine, and used FEES as the gold standard like Leder *et al.* Furthermore, we used only seven clinical parameters, although the ones most reported, and even if our patient group is representative of the prevalence rate for German patients with HNC, the patient group is too small to carry out calculations for different tumor sites.

To our knowledge, the present study is the first to examine the predictability of clinical parameters of non-swallowing oral and laryngeal functions in patients with HNC post-surgically. Various studies carried out on neurological patients, predominantly after stroke, mostly referred to videofluoroscopy with aspiration as the main reference criterion. The use of limitation of oral intake or dysphagia in general is rare as reference criteria but is important for the patients with HNC due to the well-known high risk of malnutrition and therewith high risk of enhanced morbidity and reduced overall survival (47, 48). Furthermore, aspiration pneumonia, a common sequela, especially in silent aspiration, leads to a significant increase in mortality, comorbidities, length of hospital stay, and attendant health care costs (49) in patients with HNC, whereas early detection of dysphagia can reduce them, as proven in patients after stroke (50), and is therefore suggested for HNC. However, at present no data support the predictability of clinical examinations in patients with HNC after surgery for aspiration or limitation of oral intake. Even if their use might be of value for the therapy of patients with HNC, the clinical assessment of oral and laryngeal function analyzed in our study is not acceptable as screening for the accurate identification of aspiration and limitation of oral intake in patients with HNC postsurgically.

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