

FEES Protocol Derived Estimates of Sensitivity: Aspiration in Dysphagic Patients

Laura W. J. Baijens · Renée Speyer ·
Walmari Pilz · Nel Roodenburg

Received: 28 November 2013 / Accepted: 7 June 2014 / Published online: 10 July 2014
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Abstract Aspiration is a common phenomenon in patients with oropharyngeal dysphagia. It can be studied using fiberoptic endoscopic evaluation of swallowing (FEES). FEES is well known and widely used in the diagnosis and treatment of swallowing disorders. However, various protocols exist, and there is no consensus on the examination protocol. The objective of this prospective study was to determine the FEES protocol derived estimates of sensitivity (Se') to detection of aspiration in dysphagic patients. The study estimated the probability of aspiration as a function of the number of swallow trials in dysphagic patients using FEES. The derived sensitivity was calculated based on presence or absence of aspiration in a ten-swallow trial protocol as arbitrary 'gold standard'. Eighty-four persons were included, comprising two patient populations with oropharyngeal dysphagia. Dysphagia in one group was due to head and neck cancer and possible oncological treatment effects on swallowing; in the other it was a result of neurological disease. All patients underwent

a standardized FEES examination using ten swallows of thin liquid followed by ten swallows of thick liquid, all in boluses of 10 cc each. FEES recordings were rated for aspiration by an expert panel blinded to patients' identity and clinical history. Descriptive statistics, Kaplan–Meier survival analysis techniques, and Log Rank/Mantel–Cox tests were used. In both patient populations the aspiration risk was underestimated when using a limited number (three or four) of swallow trials. The oncology and neurology patients differed significantly in the number of swallow trials required to determine aspiration for thin liquids (median values 2 and 7 respectively, $P = 0.006$). FEES protocols using a limited number of swallow trials can underestimate the aspiration risk in both oncological and neurological patients suffering from oropharyngeal dysphagia, especially when using boluses with a thin liquid consistency.

Keywords Dysphagia · Aspiration · Reliability · Sensitivity · Assessment protocol · Fiberoptic endoscopic evaluation of swallowing · Deglutition · Deglutition disorders

L. W. J. Baijens (✉) · W. Pilz
Department of Otorhinolaryngology, Head and Neck Surgery,
Maastricht University Medical Center, P.O. Box 5800,
6202 AZ Maastricht, The Netherlands
e-mail: laura.baijens@mumc.nl

R. Speyer
School of Public Health, Tropical Medicine and Rehabilitation
Sciences, James Cook University, Townsville, QLD, Australia

R. Speyer
Department of Otorhinolaryngology and Head and Neck
Surgery, Leiden University Medical Center, Leiden,
The Netherlands

N. Roodenburg
Department of Neurology, Maastricht University Medical
Center, Maastricht, The Netherlands

Introduction

Aspiration, defined as the passage of bolus below the level of the vocal folds, is common in patients with oropharyngeal dysphagia [1–3]. Severe dysphagia can result in aspiration, aspiration pneumonia, and sudden death, and the costs associated with dysphagia-induced comorbidity are high [2]. Fiberoptic endoscopic evaluation of swallowing (FEES) offers the dysphagia professional a reliable tool in case of penetration or aspiration [4]. FEES is well tolerated, easily repeatable, and can be performed at the

bedside [5]. However, various protocols exist, and there is no consensus on the number of swallow trials, bolus consistencies, and bolus volumes to include in a FEES. Furthermore there is very little discussion in the literature that relates how effective instrumental examinations of swallowing are in their attempt to replicate a natural event of eating a meal. Some protocols are very short with very few items presented; others may last longer but involve precisely measured boluses that may not emulate natural feeding [6–9]. Also the expertise needed to interpret the anatomical and physiological findings in a FEES examination should not be disregarded [5]. Very often swallowing protocols in clinical practice start with the introduction of thicker fluids such as nectar- and honey-thickened followed by thin fluids, and finally puree and/or solid boluses [8–11]. Leder et al used a FEES protocol with approximately 5-ml-volume food boluses dyed with blue food coloring for contrast. The first food consistency introduced was puree (custard), followed by liquid (milk), and then a solid bolus (cracker) [8]. In the study by Warnecke et al patients received teaspoon-wise three different food consistencies dyed with blue food coloring for ease of visualization. The first food consistency introduced was pureed food, followed by liquid and soft solid food [9]. The choice of the number and order of swallow trials per consistency is often not based on clear scientific evidence but on clinical experience and educated based insight. The present prospective study was designed to estimate the probability of aspiration as a function of the number of swallow trials. It applies a standardized FEES protocol calling for ten consecutive swallow trials of 10 cc each in two different consistencies (first ten boluses of thin liquid, then ten boluses of thick liquid) administered to oncological and neurological patients suffering from oropharyngeal dysphagia. The order of presenting boluses of different consistencies in the current study was based on the international literature and the range of standardized protocols usually followed in clinical practice [10–12].

Materials and Methods

Participants

The patients were consecutively enrolled in the present prospective study while visiting the outpatient clinic of the Maastricht University Medical Center (MUMC) for their dysphagic complaints. Their data were collected as part of the regular healthcare program for oropharyngeal dysphagia [12] (daily clinical practice) and their inclusion took about 2 months. In this period incoming patients with oropharyngeal dysphagia could be divided into two main diagnostic groups. In the one, dysphagia was due to head and

neck cancer and possible oncological treatment effects on swallowing; in the other, dysphagia was accompanied by a neurological disease. During the patient interview all subjects reported subjective clinical complaints of oropharyngeal dysphagia ranging from mild to severe. These included, among others, slow eating due to prolonged transit times, oral or pharyngeal passage disorder, coughing while drinking, choking on foods, and aspiration pneumonia. All patients were able to perform a swallow on command. The oncological and neurological etiologies were heterogeneous. The following exclusion criteria were applied: a Mini Mental State Examination (MMSE) score below 23 [13]; concurrent head and neck cancer and a neurological disease (or neurosurgical brain intervention); a stroke less than 3 months prior; head and neck oncological treatment less than 3 months prior; surgery of the head and neck swallowing region in patients with neurological disease; extreme fatigue or weakness (unable to sit upright); an unstable period of a neurological disease (periods with large fluctuations, especially in motor function); not having had the same medication regimen for the past 6 weeks in neurological patients (i.e., with Parkinson's disease); and having undergone total laryngectomy. Informed consent was obtained from all patients. The study protocol was approved by the medical ethical committee.

Swallowing Assessment

Before the FEES, a clinical observation of oral intake by a speech and language pathologist, a detailed clinical examination by a laryngologist, and the Functional Oral Intake Scale (FOIS) [14] were performed to ensure correct inclusion. The range of scores on the FOIS is one to seven, indicating nothing by mouth (1) to total oral diet with no restrictions (7) [14]. After these preliminaries, all subjects underwent a standardized FEES protocol. During the FEES, the patients were offered ten trials of thin liquid followed by ten trials of thick consistency. Each trial contained 10 cc of water (thin liquid) or applesauce (thick liquid) and was dyed with five percent methylene blue (10 mg/ml). The applesauce changed into a thick liquid consistency after adding methylene blue. The tip of the flexible fiberoptic endoscope Pentax FNL-10RP3 (Pentax Canada Inc., Mississauga, Ontario, Canada) was positioned just above the epiglottis in the 'high position' so as not to compromise the closure of the laryngeal vestibule [5]. FEES images were obtained using an Alpatron Stroboscopic ACLS camera, Alpatron Lightsource, IVACX computerized video archiving system (Alpatron Medical Systems, Rotterdam, The Netherlands) and recorded on a DVD. Neither a nasal vasoconstrictor nor a topical anesthetic was administered to the nasal mucosa. The subjects were wearing their dental prosthesis (if present). In the

event of aspiration during a trial, the examination using this consistency was ended. Very few showed massive aspiration when offered the first consistency. Those who did were instructed to cough in order to eject the bolus, and they underwent a clinical follow-up regimen for 1 week. None of these patients developed pneumonia, and no other adverse effects were observed.

Swallows were analyzed using the visuoperceptual (dichotomous) variable of aspiration (present or absent). Any material entering the airway below the true vocal folds was defined as aspiration [3]. Prior to the actual rating procedure, a panel was formed of two experienced raters who were trained to interpret and score the dichotomous scale. After that experimental run, they carried out the procedure on the raw data, identifying and rating all swallow trials on the basis of consensus. The panel was blinded to the diagnostic group and to the identity of the patients. Each rater had more than 8 years experience in judging FEES videos in daily practice and during previous scientific studies [10, 12]. Indeed, their intrarater and interrater reliability for scoring aspiration proved reliable in previous studies (Weighted Kappa ≥ 0.60) [10]. These experts scored the blocks of FEES videos (ten swallow acts per consistency) in randomized order. Each swallow could be assessed at varying speed, ranging from normal to slow motion up to frame-by-frame, as many times as necessary. The duration of the panel sessions was limited by the raters themselves (max. 2 h per session).

Statistical Analysis

All statistical analyses were performed using IBM SPSS Statistics for Windows, Version 20.0 (IBM Corp., Armonk, New York, USA). Descriptive statistics on the number of swallow trials were assembled for each consistency separately (Table 1). Presence or absence of aspiration was determined arbitrarily at the tenth swallow trial (if applicable); If no aspiration had occurred during any of the ten consecutive trials (per consistency), the patient was declared a non-aspirator. If aspiration had occurred, that patient was considered an aspirator. FEES is considered to be a gold standard in the assessment of oropharyngeal dysphagia [15]. Sensitivity testing refers to how the final outcome of an analysis may change as a function of varying one or more of the input parameters (such as number of swallow trials) in a prescribed manner [16]. In mathematics, the prime symbol (') is generally used to generate a variable that is related or similar to an original variable or concept but not identical (notation, for example, variable x' vs variable x). To distinguish the derived estimates of sensitivity as determined in this study from sensitivity calculation using an external gold standard or different assessment tool, the variable Se' was introduced.

Derived estimates of sensitivity (Se') for aspiration were determined for the total group as a function of the number of swallow trials used in a FEES protocol. Crosstabs calculations based on a dichotomized classification (aspirator vs non-aspirator) using an arbitrarily 'gold standard' (tenth swallow trial), provided the derived sensitivity data for both consistencies separately (Table 2). Kaplan–Meier survival analysis techniques were used to visualize the occurrence of aspiration as a function of the number of swallow trials per group and consistency. The resulting differences in occurrence between the diagnostic groups were tested for significance by means of the Log Rank/Mantel–Cox test for both consistencies.

Results

Participants

The study included eighty-four mentally competent and physically stable patients (18♀, 66♂) with oropharyngeal dysphagia in two etiological groups ($N = 50$ neurology, $N = 34$ oncology). During the period of recruitment (about 8 weeks), no patients were observed with other etiologies of dysphagia such as Zenker's diverticulum, cervical spine disorders etc. The mean age of the oncological patients was 67 years, that of the neurological patients 60. The median of the FOIS score was 4 in the oncological patients and 5 in the neurological patients (Table 3). The patients of the neurology and the oncology group had very diverse etiologies (for instance: T2N2 hypopharyngeal carcinoma, stroke, Parkinson's disease with Hoehn and Yahr score II, Myotonic dystrophy with MIRS III, T3N1 oropharyngeal carcinoma etc.).

Aspiration Risk as Function of the Number of Swallow Trials in FEES

Table 1 presents descriptive data on aspiration risk for thin and thick liquid consistencies as a function of the number of trials used in FEES. The total number of patients (column 3) per trial decreases as the number of trials rises because the examination was ended when patients showed aspiration. The table gives the number of patients with and without aspiration (column 4). Fewer patients received a bolus with thick liquid than one of thin liquid (66 vs 84 subjects) because the examination of several patients was stopped after the first ten boluses for various reasons: very severe dysphagia with massive aspiration during administration of the thin consistency; exam was too tiring; unpleasant taste of the boluses, etc. Overall, the Se' increased along with the number of trials. The Se' of using one trial of thin versus thick consistency was 43.9 and

Table 1 Descriptive statistics of aspiration risk as a function of number of swallow trials in FEES

Bolus consistency	Number of swallow trial	Total number of subjects per swallow trial ^a : N_{total}	Data per swallow trial: $N_{\text{aspiration}}$ (%); N_{normal} (%)	Cumulative data: $N_{\text{aspiration}}$ (%); N_{normal} (%)	Se' of aspiration (%) per swallow trial ^b
Thin liquid (10 cc)	1	84	25 (29.8); 59 (70.3)	25 (29.8); 59 (70.3)	43.9
	2	59	9 (15.3); 50 (84.8)	34 (40.5); 50 (59.5)	59.6
	3	50	5 (10.0); 45 (90.0)	39 (46.4); 45 (53.6)	68.4
	4	45	4 (8.9); 41 (91.1)	43 (51.2); 41 (48.8)	75.4
	5	41	4 (9.8); 37 (90.2)	47 (56.0); 37 (44.0)	82.5
	6	37	3 (8.1); 34 (91.9)	50 (59.5); 34 (40.5)	87.7
	7	34	4 (11.8); 30 (88.2)	54 (64.3); 30 (35.7)	94.7
	8	30	1 (3.3); 29 (96.7)	55 (65.5); 29 (34.5)	96.5
	9	29	1 (3.5); 28 (96.6)	56 (66.7); 28 (33.3)	98.2
	10	28	1 (3.6); 27 (96.4)	57 (67.9); 27 (32.1)	NA ^c
Thick liquid (10 cc)	1	66	11 (16.7); 55 (83.3)	11 (16.7); 55 (83.3)	39.3
	2	55	7 (12.7); 48 (87.3)	18 (27.3); 48 (72.7)	64.3
	3	48	5 (10.4); 43 (89.6)	23 (34.8); 43 (65.2)	82.1
	4	43	2 (4.7); 41 (95.3)	25 (37.9); 41 (62.1)	89.3
	5	41	1 (2.4); 40 (97.6)	26 (39.4); 40 (60.6)	92.9
	6	40	0 (0); 40 (100.0)	26 (39.4); 40 (60.6)	92.9
	7	40	0 (0); 40 (100.0)	26 (39.4); 40 (60.6)	92.9
	8	40	0 (0); 40 (100.0)	26 (39.4); 40 (60.6)	92.9
	9	40	0 (0); 40 (100.0)	26 (39.4); 40 (60.6)	92.9
	10	40	2 (5.0); 38 (95.0)	28 (42.4); 38 (57.6)	NA ^c

^a N decreases with increasing number of swallow trials because for patients who aspirated the examination was ended

^b To determine Se' a hypothetical arbitrary 'gold standard' for aspiration was set at ten swallow trials. The FEES protocol's Se' for the detection of aspiration was calculated with the condition aspiration (present or absent) at the 10th swallow trial as a reference; If no aspiration had occurred during any of the ten consecutive swallows (per consistency) the patient was declared a non-aspirator, whereas if the patient aspirated on any of the ten trials that patient was considered an aspirator

^c NA: Not applicable because the condition aspiration (present or absent) at the 10th swallow trial was applied as the 'gold standard'

39.3 %, respectively. By the ninth trial it had risen to 98.2 % for a thin liquid bolus and 92.9 % for a thick one (Table 1).

Figures 1 and 2 show the cumulative percentage of patients with aspiration as a function of the number of swallow trials for thin and thick liquid boluses. The cumulative percentage of patients who aspirated at any of the ten swallow trials with thin liquid is 67.9 % (Fig. 1, Table 1). Using thick liquid, that cumulative percentage is 42.4 % (Fig. 2, Table 1).

Next, Kaplan–Meier survival analysis techniques were used to determine the probability of aspiration as a function of the number of swallow trials for each consistency and for each diagnostic group. Figure 3 shows the Kaplan–Meier curves using thin liquid for each group separately: patients with oncological disorders ($N = 34$) and patients with neurological disorders ($N = 50$). The estimated probability of aspiration using a protocol of one, three, or ten swallow trials is 46, 64, or 79 % in the oncology group compared to 17, 34, or 57 % in the neurological group. Figure 4 presents results using the

same techniques but now for thick consistency. It shows the Kaplan–Meier curves using thick liquid for each group separately: patients with oncological disorders ($N = 26$) and patients with neurological disorders ($N = 40$). The estimated probability of aspiration using a protocol of one, three, or ten swallow trials is 27, 47, or 52 % in the oncological group compared to 8, 25, or 36 % in the neurological group. None of the patients was censored due to a 'competing risk event', which may preclude the event of interest (aspiration) or modify the probability of its onset [17]. To detect differences in the median number of swallow trials necessary to reveal aspiration, data were tested for significant differences between oncological patients and neurological patients using the Log Rank/Mantel–Cox test. Significant group differences were found regarding the median number of swallow trials necessary to reveal aspiration for thin liquid. The oncology and neurology patients differed significantly in this regard (median values 2 and 7, respectively, $P = 0.006$), though not for thick liquid (median values 4 and 10, respectively, $P = 0.123$).

Table 2 Derived estimates of sensitivity (Se') to aspiration were determined using the data from column 5, Table 1 in the crosstabs calculations below

Thin liquid	Aspiration 1st swallow	No aspiration 1st swallow	Total
Aspiration (10th swallow)	25	32	57
No aspiration (10th swallow)	0	27	27
Total	25	59	84
Thin liquid	Aspiration 2nd swallow	No aspiration 2nd swallow	Total
Aspiration (10th swallow)	34	23	57
No aspiration (10th swallow)	0	27	27
Total	34	50	84

To determine sensitivity (Se') values per swallow trial, crosstabs calculations were used for both consistencies separately. The 10th swallow trial was used as the arbitrary gold standard

Sensitivity (Se') for aspiration at 1st swallow trial = $25/(25 + 32) = 43.9\%$

Sensitivity (Se') for aspiration at 2nd swallow = $34/(34 + 23) = 59.6\%$, etc.

Discussion

These preliminary results suggest that dysphagic patients who are at risk for aspiration will not always be identified as such when using a FEES protocol with few (just three or four) swallow trials. After three trials (thin consistency), 39 (46.4 %) patients were identified as aspirators and 45 (53.6 %) as non-aspirators (Table 1, column 5). At the tenth trial, however, 57 (67.9 %) patients were identified as aspirators and 27 (32.1 %) as non-aspirators. During a FEES in clinical practice, an attempt is made to ascertain the risk of aspiration during daily oral intake. However, no validated FEES protocol exists that recommends a minimum number of swallow trials or order for presenting consistencies to ensure a reliable estimate. Therefore, a tenth swallow trial was adopted as the 'gold standard' to determine the Se' of various protocols. The arbitrary cut-off of ten swallows per consistency was a balance between acceptable FEES protocol for the patients (20 swallows in total) and a cut-off providing sufficient data for the present study. The Se' for detecting aspiration of thin fluids as a function of the number of swallow trials in the total patient group was between 43.9 % (first trial) and 98.2 % (ninth). The Se' for detecting aspiration of thick fluids as a function of the number of swallow trials was between 39.3 % (first trial) and 92.9 % (ninth). These differences in sensitivity estimations between the thin and the thick liquid swallows should be interpreted carefully because the number of patients swallowing thick liquid was smaller than the patients swallowing thin liquid boluses as described above (Table 1, column 3).

High sensitivity is a desirable quality in an assessment tool. These results suggest that a high proportion of true positives (i.e., aspirators) are correctly identifiable after

Table 3 Patient characteristics

Patient population	<i>N</i>	Gender	Mean age (Range; Std. deviation)	Median FOIS (Range; Std. deviation)
Total population	84	18♀, 66♂	63 (21-85; 15.5)	5 (1-7; 1.7)
Neurological subjects	50	13♀, 37♂	60 (21-85; 17.8)	5 (2-7; 1.2)
Oncological subjects	34	5♀, 29♂	67 (30-83; 10.4)	4 (1-7; 1.9)

ten swallow trials using the present FEES protocol. The Kaplan–Meier techniques revealed a higher probability of aspiration as a function of the number of trials (for both consistencies) among oncological patients compared with neurological patients (Figs. 3, 4). However, comparing the number of swallow trials necessary to detect aspiration for thin liquid, the oncology and neurology patients proved to differ significantly (median values 2 and 7, respectively, $P = 0.006$). However, drawing clinical conclusions from this group difference (neurology vs oncology patients) might be too speculative at this point. Despite the high Se' for detecting aspiration using ten swallow trials, aspiration will not have occurred in all patients by the tenth one (Table 1, column 4). For these patients, survival time is said to be censored; if and when a patient will experience aspiration in the future is unclear at the tenth trial. In daily practice, however, patients will probably undergo a FEES consisting of three or four swallow trials. In light of the preliminary data, such protocols may increase the risk of identifying potential aspirators as non-aspirators. Whether FEES can rightly be called the gold standard for

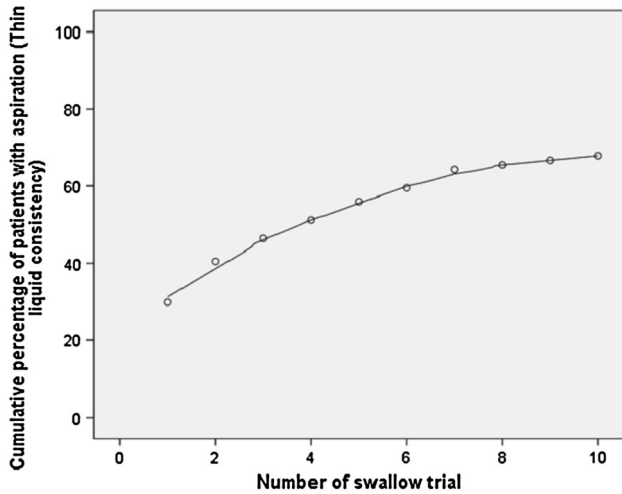


Fig. 1 Cumulative percentage of patients with thin liquid aspiration, per swallow trial for the total group (N = 84)

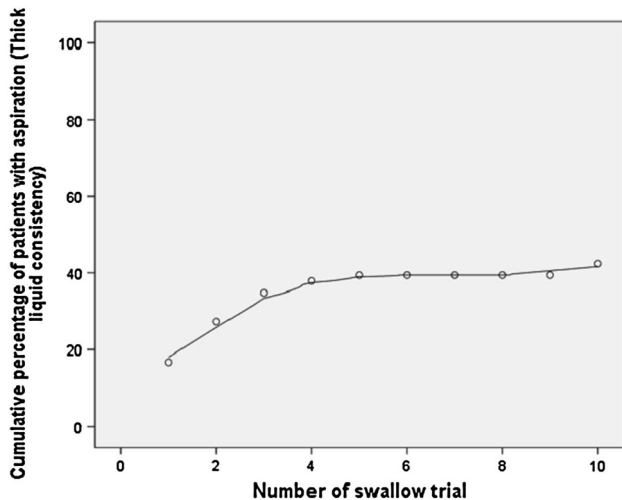


Fig. 2 Cumulative percentage of patients with thick liquid aspiration, per swallow trial for the total group (N = 66)

detecting aspiration in dysphagic patients depends on which protocol is applied. If a cut-off value of 70 % Se' is set, the number of swallow trials can be limited to three or four, as demonstrated here. However, if assigning a particular protocol the status of gold standard is supposed to ensure that every aspirator is identified (Se' 100 %), then the number of swallow trials it requires should be increased drastically. Most FEES protocols contain fewer swallow trials than the one discussed here [7–10]. The present prospective study was designed to estimate the probability of aspiration as a function of the number of swallow trials using a standardized FEES protocol of ten consecutive swallow trials of 10 cc each for two different consistencies (thin and

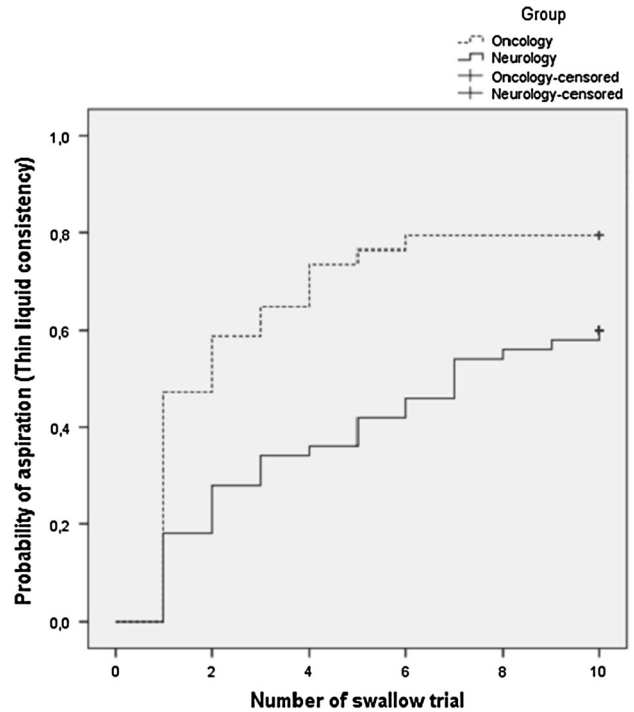


Fig. 3 Kaplan-Meier survival analysis for the oncological group (N = 34) and neurological group (N = 50): Probability of aspiration as a function of the number of swallow trials using thin liquid

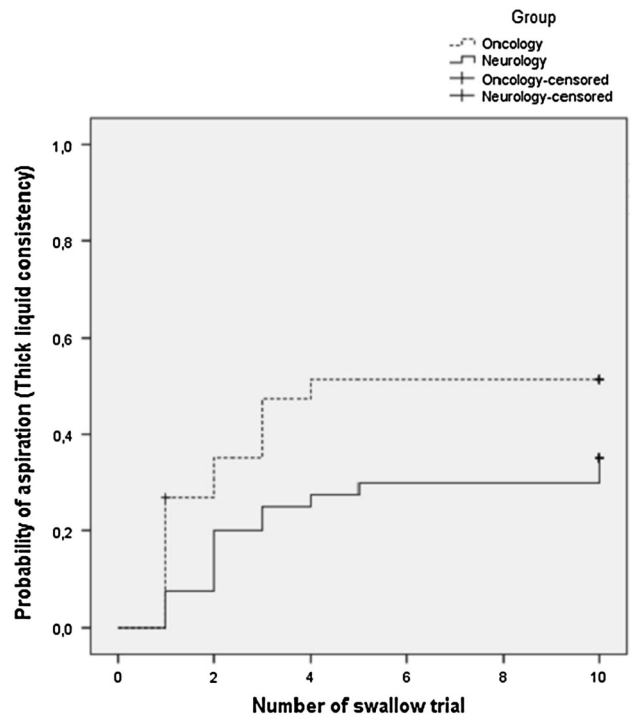


Fig. 4 Kaplan-Meier survival analysis for the oncological group (N = 26) and neurological group (N = 40): Probability of aspiration as a function of the number of swallow trials using thick liquid

thick liquid) in a group of dysphagic patients. At this moment there is no literature on validated FEES protocols that require a minimum number of swallow trials or order of consistencies to make a reliable estimate of the probability of aspiration. Future research will need to focus on the effects of changing consistencies and volumes in relation to the sensitivity of different FEES protocols.

Ideally, similar studies may be conducted to gain deeper insight in the application of other instrumental assessments of swallowing and how the number of bolus presentations given to the patient may modulate the likelihood of eliciting aspiration. Aspiration during FEES is not the only variable or assessment method to which the content of a dysphagia rehabilitation or treatment plan is based in the MUMC outpatient clinic. However, it is an important clinically relevant parameter that reflects the severity of oropharyngeal dysphagia. FEES should be used complementary to other assessment tools in order to gain a deeper insight in the swallowing pathophysiology and to set up an individualized dysphagia treatment plan.

The intention of the current study is not to promote this specific FEES protocol. One should be very careful to consider these results and possible consequences for diagnostic and/or therapeutic strategies in daily clinical practice. These preliminary data evoke more questions and motivate us for subsequent studies on the number of swallow trials and order/composition of the consistencies used in FEES.

Limitations of the study

The present prospective study has some limitations with respect to methodology and study design. A cross-over study design regarding the presentation of the bolus consistency (thin or thick liquid) may have prevented an order effect if present. Still, the order of the consistencies, thin liquid boluses followed by thick liquid boluses, was based on protocols of daily clinical practice and previous scientific studies [10, 12]. The blinded raters, however, scored the blocks of FEES videos (ten swallow acts per consistency) in randomized order.

Conclusion

FEES is a valuable tool for determining aspiration risk. But as the data presented here suggest, FEES protocols with a limited number of swallow trials can underestimate that risk for certain patients. The probability of detecting aspiration using FEES will vary depending on the applied protocol (regarding consistencies offered, number of

swallow trials, etc.). To qualify as a gold standard, a FEES protocol would have to identify every aspirator (sensitivity 100 %); to do so, the number of swallow trials should be increased drastically. Whether or not a particular FEES protocol is sensitive enough to be taken as a gold standard is therefore highly dependent on the number of swallow trials offered to the patient. Further research on this matter is recommended.

Conflict of interest The authors have no conflict of interest.

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- Laura W. J. Baijens** MD, PhD
Renée Speyer MS, SLP, PhD
Walmari Pilz MS, SLP
Nel Roodenburg SLP