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Complete List of Authors:	Braun, Tobias; Universitatsklinikum Giessen und Marburg Standort Giessen, Department of Neurology Juenemann, Martin; Universitatsklinikum Giessen und Marburg Standort Giessen, Department of Neurology Viard, Maxime; Universitatsklinikum Giessen und Marburg Standort Giessen, Department of Neurology Meyer, Marco; Universitatsklinikum Giessen und Marburg Standort Giessen, Department of Neurology Fuest, Sven; Universitatsklinikum Giessen und Marburg Standort Giessen, Department of Neurology Reuter, Iris; Universitatsklinikum Giessen und Marburg Standort Giessen, Department of Neurology Kaps, M; JustusLiebig Universit&#65533;t Giessen Prosiegel, Mario; Institute of German Linguistics Tanislav, Christian; Universitatsklinikum Giessen und Marburg Standort Giessen, Department of Neurology
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Value of Flexible endoscopic evaluation of swallowing (FEES) in neurological patients

Tobias Braun*, MD[1]; Martin Juenemann, MD, M.Sc[1]; Maxime Viard, MD[1]; Meyer, Marco, MD[1]; Fuest, Sven, MD[1]; Iris Reuter, MD, PhD [1]; Manfred Kaps, MD, PhD[1], Mario Prosiegel, MD[2]; Christian Tanislav, MD[1]

Authors' affiliations:

[1] Department of Neurology, University Hospital Giessen and Marburg, Klinikstrasse 33, 35392 Giessen, Germany.

[2] Institute of German Linguistics, Lecturer for postgraduate master's speech therapy degrees, Schellingstr. 3, Ludwig-Maximilians-University, 80802 Munich, Germany.

***Corresponding Author:** Tobias Braun, Department of Neurology, University hospital Giessen und Marburg, Klinikstrasse 33, 35392 Giessen, Germany, tel. +49-641-985-56827, fax +49-641-985-45301, tobias.braun@neuro.med.uni-giessen.de

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Abstract

Objectives: Flexible nasolaryngeal endoscopy (FEES) to detect dysphagia is gaining more importance as a diagnostic tool. Therefore, we investigated the impact of FEES in neurological patients examined in a clinical setting.

Design: Observational diagnostic study

Setting: Primary acute care in a neurological department of a German university hospital.

Participants: 241 patients with various neurological diseases who underwent FEES-procedure.

Primary and secondary outcome measures: Dysphagia and related comorbidities.

Results: 267 FEES were performed in 241 patients with various neurological diagnoses. Dysphagia was diagnosed in 68.9% of the patients. In only 33.1% of the patients appropriate oral diet was chosen prior to FEES. A relevant dysphagia occurred more often in patients with structural brain lesions (83.1% vs. 65.3%, p=0.001), dysphagic patients had a longer hospitalisation (median 18 [IQR 12-30] vs. 15 days [IQR 9.75-22.75], p=0.005) and a higher mortality (8.4% vs. 1.3%, p=0.041). When oral diet was changed, we observed a lower pneumonia rate (36% vs. 40.4%, p=0.051) and lower mortality (3.7% vs 10%, p=0.043). A restriction was identified more often in older patients (median: 75 years [IQR 66.3-82 years] versus median 72 years [IQR 60-79 years); p=0.01) and in patients with structural brain lesions (86.8% vs. 73.1%; p=0.05).

Conclusion: By clinical investigation, dysphagia was misjudged in the majority of the patients. FEES might help to compensate this drawback, revising the diet regime in nearly 70 % of the patients.

Trial registration: The study was not registered.

Strengths and limitations:

- Performance of FEES by experienced examiners in a standardised manner
- Considering the current literature, our study included the highest number (n=241) of neurological patients systematically examined with the FEES procedure

- The study design represents the clinical routine with a pre-selection of patients by using a BSE or CSE followed by instrumented diagnostics.
- Single centre study

Background

Dysphagia is a common complication in neurological diseases with aspiration pneumonia as a leading cause of death in stroke, multiple sclerosis, amyotrophic lateral sclerosis, Parkinson disease or dementia [1–5]. In elderly patients suffering from infections, a concomitant aspiration pneumonia results in increased morbidity and mortality [6, 7]. Dysphagia determines therefore proximately the prognosis in ill patients, an due to the functional link to the central and peripheral nerve system, it is of particular relevance in neurological patients [7].

Apart from physical examination performed by physicians or speech and language therapists, diagnostic tools were developed to investigate the swallowing function [8]. Two procedures, the videofluoroscopic evaluation of swallowing (VFSS) and the flexible nasolaryngeal endoscopy of swallowing (FEES) entered the clinical practice for this purpose. The latter works without radiation exposure and it can be easily repeated; it can be performed at bedside and even in uncooperative or unconscious patients. FEES is therefore gaining more importance in the examination of neurological patients [9, 10]. However currently systematic investigations providing the overall benefit of this procedure in neurological patients are missing.

Therefore, the aim of the presented study is to assess the value of FEES in unselected neurological patients regarding the benefit in judging the swallowing function and the related short term outcome.

Methods

FEES was performed in stroke patients with pathological bedside screening examination (BSE), in patients with other etiologies, when there were pathological findings in the comprehensive swallowing examination (CSE) performed by a speech and language therapist (SLT). Indication for CSE was clinical suspicion of dysphagia, i.e. in patients with newly diagnosed motorneurone disease or in those showing clinical signs of dysphagia (e.g. wet voice and/or coughing when drinking, etc.). In our department, we use the Gugging Swallowing Screen (GUSS) [11] as screening instrument for stroke-associated dysphagia. Oral diet prior to FEES was chosen by the attending physician and a SLT based on the findings in the CSE. In stroke patients, oral diet was chosen according to the instructions of the GUSS. For quality control reasons, findings gathered in examinations were documented systematically. All FEES procedures were performed in standardized manner by experienced physicians (see below).

Patients

All patients treated in our department from January 2014 to September 2016, who underwent FEES were considered for the analysis. Data documented in the database included: age, sex, length of stay in hospital, diagnosis, presence of brain lesions (such as new or old ischemic stroke, intracerebral bleeding, tumour, cerebral atrophy, etc.), occurrence of pneumonia (defined as clinical diagnosis of pneumonia; determined by the treating physician), treatment on intensive care unit, mortality, presence of dysphagia and type of oral intake (before and after FEES). For data acquisition and use for scientific analyses, an ethical approval was obtained from the local ethical committee (Justus-Liebig-University, Giessen; protocol number 208/16).

FEES – Flexible endoscopic evaluation of swallowing

FEES is a videoendoscopic nasolaryngeal swallowing study. We performed FEES following the standardised FEES® protocol according to Langmore [12]: A small endoscope (about 4 mm in diameter) was introduced through the inferior nasal meatus and the epipharynx in the mesopharynx. Swallowing of saliva and different consistencies of food and liquids, penetration, aspiration,

localization and amount of residues as well as patients' reactions (such as coughing) were visualised and documented. By definition, penetration is entering of any material into the airway (above the level of the vocal folds), aspiration means entering of any material below the level of the vocal folds. In the first step of the procedure, anatomical changes, management of saliva and movements of swallowing related structures were assessed. Then, we tested pudding-thick consistency (thickened water), normal water and solid food. All consistencies were applied three times. If a consistence appeared unsafe, we skipped the corresponding consistence. Based on the findings in FEES, the appropriate oral diet was chosen for the patients. All FEES procedures were performed or supervised by an experienced investigator.

Outcome measurements

Oral intake and dysphagia severity were measured by use of the functional oral intake scale (FOIS) and the Fiberoptic Endoscopic Dysphagia Severity Score (FEDSS), respectively:

FOIS is a seven-tiered scale ranging from 1 = no oral intake at all (NPO= nil per os) to 7 = full oral intake without restrictions (**Appendix 1**) [13]. The data of the functional oral intake scale were categorised in either NPO (FOIS=1), partial oral intake (FOIS =2-6) and full oral intake (FOIS=7). De-escalation of oral diet was defined as a positive change on the FOIS, whereas restriction of oral diet was defined as a negative change.

For defining the overall severity of dysphagia, we used the FEDSS-scale developed by Dziewas and co-workers [14]. The FEDSS (Fiber Endoscopic Dysphagia Severity Score) is a six-tiered scale originally designed for use in stroke patients (**Appendix 2**). All parameters are recorded in a standardised way.

For evaluating the value of performing FEES in neurological patients, the following parameters were correlated with baseline data and dependent factors:

- Dysphagia as defined by a FEDSS score of $\geq$ 2
- Oral intake status as calculated by the FOIS and its overall change and type of change after FEES

Statistical analyses

Absolute and relative frequencies were calculated based on cross-tables. For comparing relative a two-tailed Fisher's exact test was used. Continuous variables were analysed by calculating the median value and the interquartile range (25%-percentile and 75%-percentile). Nonparametric data were analysed employing the Mann–Whitney U-test. All statistical analyses were performed with the SPSS, release version 22.0 (©SPSS, Inc., IBM Company, 2015, Chicago-IL).

Results

Patients' characteristics

In 241 patients, 267 FEES were performed. In 23 patients (9.5%), the procedure was repeated at least once. Among those patients, in 12 persons an improvement of dysphagia was noted (52.1%), in one patient the subsequent examination revealed an increased severity of dysphagia and in a second patient, previously diagnosed with no dysphagia, aspiration was detected during a repeated examination.

140 patients were male (52.4%), the median age was 73 years (IQR [interquartile range] 61-80 years). 109 patients (45.2%) were treated on the intensive care unit. In 46.8% of the patients, an ischemic stroke was diagnosed. The different disease entities detected in our patients are summarized in **Figure 1**. The group classified as "other" consisted of patients with heterogenous diagnoses (epileptic seizures, dementia, Guillain Barré-syndrom, degenerative changes of the cervical spine, etc.).

187 patients had a brain lesion detected in CT-scan or MRI (8 tumours, 125 new ischemic lesions, 27 bleedings, 27 other lesions [old ischemic lesions, unspecific white matter lesions, cortical atrophy, etc.]). 98 patients (40.7%) developed pneumonia, 15 patients died during hospitalisation (6.2%). Initially, 140 patients (52.4%) had no oral intake (NPO), 58 patients (24.1%) partial oral intake and 43 patients (16.1%) full oral intake. 108 patients (44.8%) were dependent on nasogastric feeding tube prior to FEES and 7 patients (2.9%) on a PEG (percutaneous endoscopic gastrostomy)-tube. Patients' characteristics are presented in **Table 1**.

No side effects, i.e. laryngospasm, syncope or non-self-limiting epistaxis occurred, 2 patients (0.8%) had mild epistaxis after FEES.

FEES Examination

The median overall FEDSS score in the entire study population was 4 (IQR 1-6). FEES revealed no sign of dysphagia (FEDSS=1) in 75 patients (31.1%), whereas dysphagia (FEDSS 2-6) was diagnosed in 166 persons (68.9%).

Oral diet was more often de-escalated in patients without dysphagia (72.8% vs. 25.3%, p<0.0001) and was more often restricted in patients with dysphagia patients with normal swallowing function (2.5% vs. 36.6%, p<0.001). In 26 patients (10.8%) with full oral intake, FEES unveiled a critical dysphagia and as a result, the diet strategy was revaluated. Out of these 26 patients, 16 (61.5%) had partial oral intake and 38.5% patients had NPO after FEES. Changes in oral diet after FEES can be seen in **Figure 2**.

Dysphagia was diagnosed more often in patients with brain lesions (65.3% vs. 83.1%; p=0.001). Patients with dysphagia had a longer length of stay in hospital (median 15 [IQR 9.75-22.75] vs. 18 [IQR12-30] days, p=0.005) and a higher mortality (8.4% vs. 1.3%, p=0.041. Results are summarized in **Table 1**.

Differences between patients with change in oral diet

A total of 161 patients (66.8%) had a change in oral diet, 93 patients (57.8%) were de-escalated and in 68 patients (42.2%) a restriction followed. Out of 68 patients restricted in oral diet after the examination, in 47 (69.1%) NPO was recommended. Patients without change in oral diet had a higher rate of pneumonia (40.4% vs. 36%, p=0.051) and a higher mortality as compared to those with change in oral diet (10% vs 3.7%, p=0.043). Results are summarized in **Table 2**.

Differences between patients with de-escalation and restriction of oral diet

Restriction in oral diet was indicated more often than de-escalation in older patients (median 72 [IQR 60-79) vs 75 [IQR 66.25-82] years old, p=0.01). In patients with ischemic stroke (64.7% vs. 46.2%, *p*=0.025) or other brain lesions (86.8% vs. 73.1%, *p*=0.05) restriction of oral diet occurred more often than de-escalation. There was higher mortality in patients with restriction in oral diet as compared to de-escalated patients (7.4% vs. 1.1%, *p*=0.082). Results are summarized in **Table 3**.

Discussion

In 241 unselected neurological patients, FEES unveiled relevant dysphagia in 166 (68.9%) individuals. After performing the FEES, the diet management was revised in 66.8% of the patients. A restriction in oral intake was indicated predominantly in elderly patients and in those suffering from stroke or those with other structural brain lesion. Relevant dysphagia was associated with higher mortality and longer duration of hospitalization.

In different investigations dysphagia was identified as strong factor associated with worse outcome in many disorders [1–5, 15–17][1-6. 15-17]. Therefore establishing the right diagnosis with initiation of appropriate therapeutic measures is of major relevance. In this context, FEES seems to be a promising tool for identifying patients at risk. With this procedure, we identified in our study in considerable proportion of patients a relevant dysphagia which led to a proximate adjustment in oral diet. In line with investigations in other populations in our study patients diagnosed with dysphagia had a longer period of hospitalisation and a higher risk for poor outcome. It could be expected pneumonia is the main complication associated with a poor outcome; however, our analysis showed no significant differences in pneumonia rates between patients with versus without dysphagia. It seems in neurological patients some other factors might determine the development of dysphagia. As demonstrated in our study dysphagia was associated with the presence of structural brain lesions, which could be attributed to complexity of the swallowing process. It is controlled and regulated by

complex supra-medullary networks, so brain lesions causing relevant swallowing-dysfunction seems to be an appropriate finding [18, 19] .

In only 33.1% of the investigated patients, the initial diet regime was confirmed after performance of FEES. Despite extensive clinical expertise the established diagnosis regarding swallowing function was incorrect in nearly every second patient; 10.8% of patients had full oral intake although they needed a restriction. Low awareness for dysphagia, the inability of clinical examination and screening tests to detect silent aspirations or to methodological reasons might also explain this result [20,]. Therefore, our results underline the necessity of performing elaborate dysphagia diagnostics routinely and it also supports recent trends implementing FEES examination as standard procedure in severely affected neurological patients.

A restriction in oral diet was indicated more often in older patients. The physiological function decline, also called “presbyphagia”might be responsible for this observation[21]. Since the vast majority of neurological patients in general are of advanced age, these factors need to be considered, when interpreting FEES findings. A structural brain lesion in addition to pre-existing presbyphagia might explain the pronounced severity of dysphagia in our study group.

The selection bias considering a large number of intensive care patients needs consideration when interpreting our results. Since those patients are more severely affected, i.e. by stroke, our findings could have overestimated the number of neurological patients affected by dysphagia, which might also explain the high frequency of pneumonia as compared to other researchers [22]. Because of ethical reasons, we used no control group (without FEES): The risk of pneumonia and pneumonia-related death would have been too high. These are the main limitations of the study. However, the study design represents the clinical routine with a pre-selection of patients by using a BSE or CSE followed by instrumented diagnostics. Only one study by Bax and co-workers was published on

the effect of FEES on outcome in 220 neurological patients [23]. However, in this study only some patients underwent FEES. In our study all 241 patients underwent FEES procedure.

Conclusions

Using FEES, we could detect signs of dysphagia in 68.9% of our neurological patients. Dysphagia was associated with the presence of structural brain lesions, higher mortality and longer duration of hospitalization. Changing of oral diet was associated with a lower incidence of pneumonia and lower mortality. Only 33.1% of the patients had adequate oral diet. As most screening tests for dysphagia do not cover non-stroke patients and cannot detect silent aspiration, using FEES at low-threshold in all neurological patients might help identifying patients at risk with this safe and fast bed-side assessment tool. It ensures safety when deciding on the type of oral intake and brings the benefit of a markedly reduction in mortality and morbidity.

Appendix 1 - Functional oral intake scale [13]

1	Nothing by mouth (NPO)
2	Tube dependent with minimal attempts of food or liquid
3	Tube dependent with consistent oral intake of food or liquid
4	Total oral diet of a single consistency
5	Total oral diet with multiple consistencies, but requiring special preparation or compensations
6	Total oral diet with multiple consistencies without special preparation, but with specific food limitations
7	Total oral diet with no restrictions

Appendix 2- FEDSS-Score [14]

Score		Main findings
6	Handling of secretions/Saliva	Penetration or Aspiration
5	Puree consistency	Penetration/Aspiration without or insufficient protective reflex
4		Penetration/Aspiration with sufficient protective reflex
4	Liquids	Penetration/Aspiration without or insufficient protective reflex
3		Penetration/Aspiration with sufficient protective reflex
2	Soft solid food	Penetration/Aspiration or massive residues in valleculae or pyriforms
1		No penetration/aspiration and not more than mild to moderate residues in valleculae or pyriforms

List of abbreviations

BSE bedside screening examination

CSE comprehensive swallowing examination (CSE)

CT computed tomography

FEDSS fiberendoscopic dysphagia severity scale.

FEES flexible endoscopic evaluation of swallowing

FOIS functional oral intake scale

GUSS Gugging Swallowing Screen

IQR interquartile range

MRI magnet resonance imaging

NPO nil per os (no oral intake)

PEG percutaneous endoscopic gastrostomy tube

SLT speech and language therapist

VFSS videofluoroscopic swallowing study

Declarations

Ethics approval and consent to participate: For the data acquisition and using them for scientific analyses an ethical approval was obtained from the local ethical committee (Justus-Liebig university, protocol number 208/16).

Consent for publication: Not applicable.

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Data sharing statement: The authors declare that the data supporting the findings of this study are available within the article. The data that support the findings of this study are not publically available due to local medical data protection policies.

Authors contributions: TB, MV and MM performed FEES examinations. TB and CT wrote the manuscript. TB, IR and MV reanalysed the examination videos when necessary. All authors were involved in the analysis and interpretation of findings. They proved the manuscript und contributed for important intellectual content. All authors contributed to writing and approved the final manuscript.

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Figures

Figure 1 – Disease entities detected in patients in percentage and absolute

Figure 2 - Decisions after FEES in patients

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Table 1. Baseline characteristics in neurological patients and differences in patients with and without dysphagia

	Total cohort (n=241)	Normal swallowing function (n=75)	Relevant dysphagia (n=166)	*P*
Sex (number of male patients)	140 (58.1%)	41 (54.6%)	99 (59.6%)	0.401
Age (median, IQR)	73 (61-80)	71.5 (59-79.5)	73 (62-81)	0.261
Ischaemic stroke	125 (51.9%)	34 (45.3%)	91 (57.8%)	0.165
Intensive care unit	109 (45.2%)	34 (45.3%)	75 (45.2%)	<0.999
Brain lesion	187 (77.6 %)	49 (65.3%)	138 (83.1%)	**0.001**
Pneumonia	98 (40.7%)	28 (37.3%)	70 (42.2%)	0.481
Length of stay in hospital in days (median, IQR)	17 (11-29)	15 (9.75-22.75)	18 (12-30)	**0.005**
Death	15 (6.2%)	1 (1.3%)	14 (8.4%)	**0.041**
Change in oral diet	176 (65.9%)	61 (75.3%)	115 (61.8%)	0.36
Restriction	70 (26.2%)	2 (2.5%)	68 (36.6%)	**>0.001**
NPO started	47 (17.6%)	0 (0%)	47 (25.3%)	
De-escalation	106 (39.7%)	59 (72.8%)	47 (25.3%)	**>0.001**
PEG on admission	7 (2.9%)	3 (4%)	4 (2.4%)	0.682

PEG procedure in hospital	49 (20.3%)	14 (18.7%)	35 (21.1%)	0.731
PEG at discharge	54 (22.4%)	17 (22.7%)	37 (22.3%)	<0.999

IQR refers to interquartile range

NPO refers to nil per os (no oral intake)

PEG refers to percutaneous endoscopic gastrostomy tube

Table 2. Baseline characteristics in neurological patients and differences in patients with and without change in oral diet

	Total cohort (n=241)	No change in oral diet (n=80)	Change in oral diet (n=161)	*P*
Sex (number of male patients)	140 (58.1%)	45 (56.3%)	95 (59%)	0.782
Age (median, IQR)	73 (61-80)	74.5 (60.25-80.75)	72 (61-80)	0.286
Ischaemic stroke	125 (51.9%)	38 (47.5%)	87 (54%)	0.412
Intensive care unit	109 (45.2%)	43 (53.8%)	66 (41%)	**0.074**
Brain lesion	187 (77.6 %)	60 (75%)	127 (78.9)	0.515
Pneumonia	98 (40.7%)	40 (50%)	58 (36%)	0.051
Length of stay in hospital in days (median, IQR)	17 (11-29)	17.5 (12-33)	17 (11-26)	0.242
Death	15 (6.2%)	9 (11.3%)	6 (3.7%)	**0.043**
PEG on admission	7 (2.9%)	5 (6.3%)	2 (1.2%)	**0.042**
PEG procedure in hospital	49 (20.3%)	17 (21.3%)	32 (19.9%)	0.865
PEG at discharge	54 (22.4%)	20 (25%)	34 (21.1%)	0.515

IQR refers to interquartile range

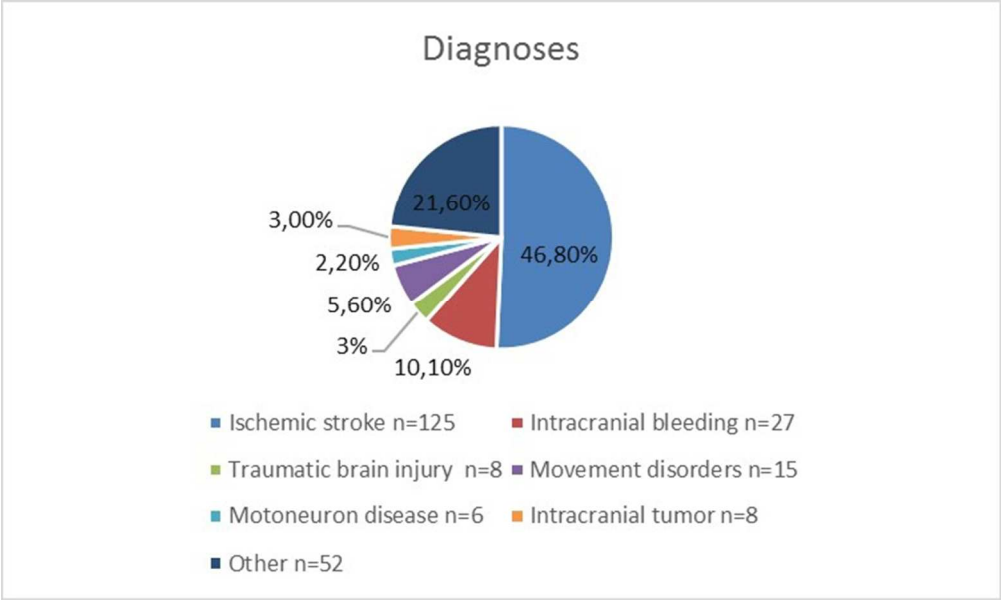
PEG refers to percutaneous endoscopic gastrostomy tube

Table 3. Differences in patients with de-escalation or restriction of oral diet

	Change in oral diet (n=161)	De-escalation of oral diet (n=93)	Restriction of oral diet (n=68)	*P*
Sex (number of male patients)	95 (59%)	55 (59.1%)	40 (58.8%)	<0.999
Age (median, IQR)	72 (61-80)	72 (60-79)	75 (66.25-82)	**0.01**
Ischaemic stroke	87 (54%)	43 (46.2%)	44 (64.7%)	**0.025**
Intensive care unit	66 (41%)	49 (52.7%)	17 (25%)	**0.001**
Brain lesion	127 (78.9)	68 (73.1%)	59 (86.8%)	**0.05**
Pneumonia	58 (36%)	38 (40.9%)	20 (29.4%)	0.183
Length of stay in hospital in days (median, IQR)	17 (11-26)	17 (11.75-27.25)	18 (11-31)	0.95
Death	6 (3.7%)	1 (1.1%)	5 (7.4%)	**0.082**
PEG on admission	2 (1.2%)	2 (2.2%)	0	
PEG procedure in hospital	32 (19.9%)	19 (20.4%)	13 (19.1%)	<0.999
PEG at discharge	34 (21.1%)	21 (22.6%)	13 (19.1%)	0.697

IQR refers to interquartile range

PEG refers to percutaneous endoscopic gastrostomy tube



Disease entities detected in patients in percentage and absolute

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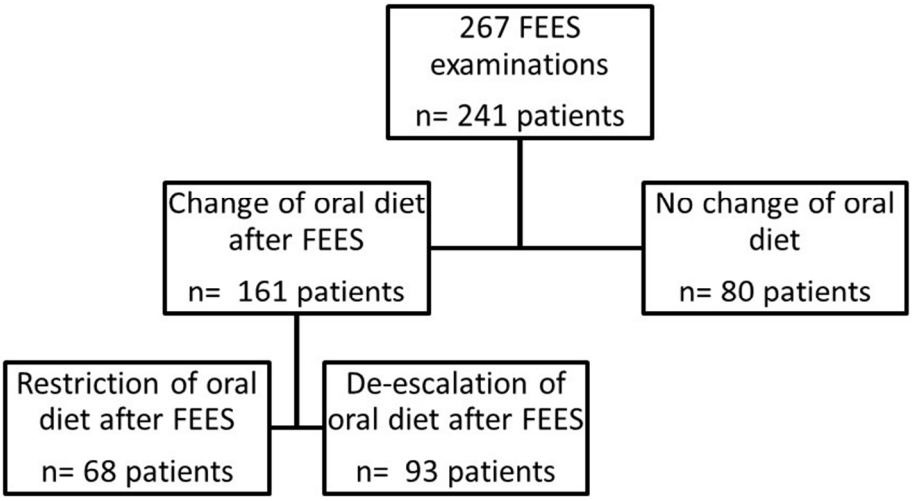

Decisions after FEES in patients

157x78mm (150 x 150 DPI)

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Value of Flexible endoscopic evaluation of swallowing (FEES) in neurological patients - A cross-sectional hospital-based registry

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Complete List of Authors:	Braun, Tobias; Universitatsklinikum Giessen und Marburg Standort Giessen, Department of Neurology Juenemann, Martin; Universitatsklinikum Giessen und Marburg Standort Giessen, Department of Neurology Viard, Maxime; Universitatsklinikum Giessen und Marburg Standort Giessen, Department of Neurology Meyer, Marco; Universitatsklinikum Giessen und Marburg Standort Giessen, Department of Neurology Fuest, Sven; Universitatsklinikum Giessen und Marburg Standort Giessen, Department of Neurology Reuter, Iris; Universitatsklinikum Giessen und Marburg Standort Giessen, Department of Neurology Kaps, M; JustusLiebig Universit&#65533;t Giessen Prosiegel, Mario; Institute of German Linguistics Tanislav, Christian; Universitatsklinikum Giessen und Marburg Standort Giessen, Department of Neurology
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Value of Flexible endoscopic evaluation of swallowing (FEES) in neurological patients - A cross-sectional hospital-based registry

Tobias Braun*, MD[1]; Martin Juenemann, MD, M.Sc[1]; Maxime Viard, MD[1]; Meyer, Marco, MD[1]; Fuest, Sven, MD[1]; Iris Reuter, MD, PhD [1]; Manfred Kaps, MD, PhD[1], Mario Prosiegel, MD[2]; Christian Tanislav, MD[1]

Authors' affiliations:

[1] Department of Neurology, University Hospital Giessen and Marburg, Klinikstrasse 33, 35392 Giessen, Germany.

[2] Institute of German Linguistics, Lecturer for postgraduate master's speech therapy degrees, Schellingstr. 3, Ludwig-Maximilians-University, 80802 Munich, Germany.

***Corresponding Author:** Tobias Braun, Department of Neurology, University hospital Giessen und Marburg, Klinikstrasse 33, 35392 Giessen, Germany, tel. +49-641-985-56827, fax +49-641-985-45301, tobias.braun@neuro.med.uni-giessen.de

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Abstract

Objectives: Fiberendoscopic evaluation of swallowing (FEES) to detect dysphagia is gaining more importance as a diagnostic tool. Therefore, we investigated the impact of FEES in neurological patients examined in a clinical setting.

Design: Observational diagnostic study

Setting: Primary acute care in a neurological department of a German university hospital.

Participants: 241 patients with various neurological diseases who underwent FEES-procedure.

Primary and secondary outcome measures: Dysphagia and related comorbidities.

Results: 267 FEES were performed in 241 patients with various neurological diagnoses. Dysphagia was diagnosed in 68.9% of the patients. In only 33.1% of the patients appropriate oral diet was chosen prior to FEES. A relevant dysphagia occurred more often in patients with structural brain lesions (83.1% vs. 65.3%, p=0.001), dysphagic patients had a longer hospitalisation (median 18 [IQR 12-30] vs. 15 days [IQR 9.75-22.75], p=0.005) and a higher mortality (8.4% vs. 1.3%, p=0.041). When oral diet was changed, we observed a lower pneumonia rate (36% vs. 50%, p=0.051) and lower mortality (3.7% vs 11.3%, p=0.043) in comparison to no change of oral diet. A restriction of oral diet was identified more often in older patients (median: 75 years [IQR 66.3-82 years] versus median 72 years [IQR 60-79 years); p=0.01) and in patients with structural brain lesions (86.8% vs. 73.1%; p=0.05).

Conclusion: On clinical investigation, dysphagia was misjudged in the majority of the patients. FEES might help to compensate this drawback, revising the diet regime in nearly 70 % of the patients.

Trial registration: The study was not registered.

Strengths and limitations:

- Performance of FEES by experienced examiners in a standardised manner

- Considering the current literature, our study included the highest number (n=241) of neurological patients systematically examined with the FEES procedure
- Single centre study

Background

Dysphagia is a common complication in neurological diseases with aspiration pneumonia as a leading cause of death in stroke, multiple sclerosis, amyotrophic lateral sclerosis, Parkinson disease or dementia [1–5]. In elderly patients suffering from infections, a concomitant aspiration pneumonia results in increased morbidity and mortality [6, 7]. Dysphagia determines therefore the immediate prognosis in ill patients, and due to the functional link to the central and peripheral nerve system, it is of particular relevance in neurological patients [7].

Apart from physical examination performed by physicians or speech and language therapists, diagnostic tools were developed to investigate the swallowing function [8]. Two procedures, the videofluoroscopic evaluation of swallowing (VFSS) and the fiberendoscopic evaluation of swallowing (FEES) entered the clinical practice for this purpose. The latter works without radiation exposure and it can be easily repeated; it can be performed at bedside and even in uncooperative or unconscious patients. FEES is therefore gaining more importance in the examination of neurological patients [9, 10]. However, systematic investigations providing the overall benefit of this procedure in neurological patients are missing currently.

Therefore, the aim of the presented study is to assess the value of FEES in unselected neurological patients regarding the benefit in judging the swallowing function and the related short term outcome.

Methods

FEES was performed in stroke patients with pathological bedside screening examination (BSE), in patients with other aetiologies, when there were pathological findings in the comprehensive swallowing examination (CSE) performed by a speech and language therapist (SLT). Indication for CSE was clinical suspicion of dysphagia, i.e. in patients with newly diagnosed motor neuron disease or in those showing clinical signs of dysphagia (e.g. wet voice and/or coughing when drinking, etc.). In our department, we use the Gugging Swallowing Screen (GUSS) as screening instrument for stroke-associated dysphagia. The GUSS consists of 4 subtests. In the first subtest, vigilance, ability to cough

and swallowing of saliva are assessed. The next three steps evaluate the patient's ability to safely swallow semi-solid, liquid and solid food. In each subtest a maximum of 5 points can be reached. The level of points determines the patient's severity of dysphagia. Due to the severity, different diet recommendations are given [11].

Oral diet prior to FEES was chosen by the attending physician and a SLT based on the findings in the CSE. In stroke patients, oral diet was chosen according to the instructions of the GUSS. For quality control reasons, findings gathered in examinations were documented systematically. All FEES procedures were performed in standardized manner by experienced physicians (see below).

Patients

All patients treated in our department from January 2014 to September 2016, who underwent FEES were considered for the analysis. Data documented in the database included: age, sex, length of stay in hospital, diagnosis, presence of brain lesions (such as new or old ischemic stroke, intracerebral bleeding, tumour, cerebral atrophy, etc.), occurrence of pneumonia (defined as clinical diagnosis of pneumonia; determined by the treating physician), treatment on intensive care unit, mortality, presence of dysphagia and type of oral intake (before and after FEES). For data acquisition and use for scientific analyses, an ethical approval was obtained from the local ethical committee (Justus-Liebig-University, Giessen; protocol number 208/16).

FEES – Flexible endoscopic evaluation of swallowing

FEES is a videoendoscopic nasolaryngeal swallowing study. We performed FEES following the standardised FEES® protocol according to Langmore [12]: A small endoscope (about 4 mm in diameter) was introduced through the inferior nasal meatus and the epipharynx in the mesopharynx. Swallowing of saliva and different consistencies of food and liquids, penetration, aspiration, localization and amount of residues as well as patients' reactions (such as coughing) were visualised and documented. By definition, penetration is entering of any material into the airway (above the level of the vocal folds), aspiration means entering of any material below the level of the vocal folds. In the first step of the procedure, anatomical changes, management of saliva and movements of

swallowing related structures were assessed. Then, we tested pudding-thick consistency (thickened water), normal water and solid food. All consistencies were applied three times. If a consistence appeared unsafe, we skipped the corresponding consistence. Based on the findings in FEES, the appropriate oral diet was chosen for the patients. All FEES procedures were performed or supervised by an experienced investigator.

Outcome measurements

Oral intake and dysphagia severity were measured by use of the functional oral intake scale (FOIS) and the Fiberoptic Endoscopic Dysphagia Severity Score (FEDSS), respectively:

FOIS is a seven-tiered scale ranging from 1 = no oral intake at all (NPO= nil per os) to 7 = full oral intake without restrictions (**Appendix 1**) [13]. The data of the functional oral intake scale were categorised in either NPO (FOIS=1), partial oral intake (FOIS =2-6) and full oral intake (FOIS=7). De-escalation of oral diet was defined as a positive change on the FOIS, whereas restriction of oral diet was defined as a negative change.

For defining the overall severity of dysphagia, we used the FEDSS-scale developed by Dziewas and co-workers [14]. The FEDSS (Fiber Endoscopic Dysphagia Severity Score) is a six-tiered scale originally designed for use in stroke patients (**Appendix 2**). All parameters are recorded in a standardised way.

For evaluating the value of performing FEES in neurological patients, the following parameters were correlated with baseline data and dependent factors:

- Dysphagia as defined by a FEDSS score of ≥ 2
- Oral intake status as calculated by the FOIS and its overall change and type of change after FEES

Statistical analyses

Absolute and relative frequencies were calculated based on cross-tables. For comparing relative a two-tailed Fisher's exact test was used. Continuous variables were analysed by calculating the median value and the interquartile range (25%-percentile and 75%-percentile). Nonparametric data were

analysed employing the Mann–Whitney U-test. All statistical analyses were performed with the SPSS, release version 22.0 (©SPSS, Inc., IBM Company, 2015, Chicago-IL).

Results

Patients' characteristics

In 241 patients, 267 FEES were performed. In 23 patients (9.5%), the procedure was repeated at least once. Among those patients, in 12 persons an improvement of dysphagia was noted (52.1%), in one patient the subsequent examination revealed an increased severity of dysphagia and in a second patient, previously diagnosed with no dysphagia, aspiration was detected during a repeated examination.

140 patients were male (52.4%), the median age was 73 years (IQR [interquartile range] 61-80 years). 109 patients (45.2%) were treated on the intensive care unit. In 46.8% of the patients, an ischemic stroke was diagnosed. The different disease entities detected in our patients are summarized in **Figure 1**. The group classified as "other" consisted of patients with heterogeneous diagnoses (epileptic seizures, dementia, Guillain Barré-syndrom, degenerative changes of the cervical spine, etc.).

194 patients (805%) had CT-imaging of the brain, 69 (28.6%) underwent MR-imaging. 48 patients (19.9%) had both, CT and MRI-scan, whereas 22 (9.1) patients had no imaging at all. 187 patients had a brain lesion detected in CT-scan or MRI (8 tumours, 125 new ischemic lesions, 27 bleedings, 27 other lesions [old ischemic lesions, unspecific white matter lesions, cortical atrophy, etc.]). 98 patients (40.7%) developed pneumonia, 15 patients died during hospitalisation (6.2%). Initially, 140 patients (52.4%) had no oral intake (NPO), 58 patients (24.1%) partial oral intake and 43 patients (16.1%) full oral intake. 108 patients (44.8%) were dependent on nasogastric feeding tube prior to FEES and 7 patients (2.9%) on a PEG (percutaneous endoscopic gastrostomy)-tube. Patients' characteristics are presented in **Table 1**.

No side effects, i.e. laryngospasm, syncope or non-self-limiting epistaxis occurred, 2 patients (0.8%) had mild epistaxis after FEES.

FEES Examination

The median overall FEDSS score in the entire study population was 4 (IQR 1-6). FEES revealed no sign of dysphagia (FEDSS=1) in 75 patients (31.1%), whereas dysphagia (FEDSS 2-6) was diagnosed in 166 persons (68.9%).

Oral diet was more often de-escalated in patients without dysphagia (72.8% vs. 25.3%, $p<0.0001$) and was more often restricted in patients with dysphagia patients with normal swallowing function (2.5% vs. 36.6%, $p<0.001$). In 26 patients (10.8%) with full oral intake, FEES unveiled a critical dysphagia and as a result, the diet strategy was revaluated. Out of these 26 patients, 16 (61.5%) had partial oral intake and 38.5% patients had NPO after FEES. Changes in oral diet after FEES can be seen in **Figure 2**. Dysphagia was diagnosed more often in patients with brain lesions (65.3% vs. 83.1%; $p=0.001$). Patients with dysphagia had a longer length of stay in hospital (median 15 [IQR 9.75-22.75] vs. 18 [IQR12-30] days, $p=0.005$) and a higher mortality (8.4% vs. 1.3%, $p=0.041$. Results are summarized in **Table 1**.

Differences between patients with change in oral diet

A total of 161 patients (66.8%) had a change in oral diet, 93 patients (57.8%) were de-escalated and in 68 patients (42.2%) a restriction followed. Out of 68 patients restricted in oral diet after the examination, in 47 (69.1%) NPO was recommended. Patients without change in oral diet had a higher rate of pneumonia (40.4% vs. 36%, $p=0.051$) and a higher mortality as compared to those with change in oral diet (10% vs 3.7%, $p=0.043$). Results are summarized in **Table 2**.

Differences between patients with de-escalation and restriction of oral diet

In the patients whose diet was changed, restriction of oral diet was indicated more often in older patients (median 75 [IQR 66.25-82] years old vs 72 [IQR 60-79) vs, p=0.01), in patients with ischemic stroke (64.7% vs. 46.2%, $p=0.025$) or patients with any other brain lesion (86.8% vs. 73.1%, $p=0.05$) as

compared to de-escalation of oral diet. There was also a higher mortality in patients with restriction in oral diet as compared to de-escalation (7.4% vs. 1.1%, *p*=0.082). Results are summarized in **Table 3**.

Discussion

In 241 unselected neurological patients, FEES unveiled relevant dysphagia in 166 (68.9%) individuals. After performing the FEES, the diet management was revised in 66.8% of the patients. A restriction in oral intake was indicated predominantly in elderly patients and in those suffering from stroke or those with other structural brain lesions. Relevant dysphagia was associated with higher mortality and longer duration of hospitalization.

Different investigations identified dysphagia as a strong factor associated with worse outcome in many disorders [1–5, 15–17]. Therefore, establishing the right diagnosis with initiation of appropriate therapeutic measures is of major relevance. In this context, FEES seems to be a promising tool for identifying patients at risk. With this procedure, a considerable proportion of patients with relevant dysphagia resulting in immediate adjustment in oral diet could be identified. In line with investigations in other populations, patients diagnosed with dysphagia in our study had a longer period of hospitalisation and a higher risk for poor outcome. It can be expected pneumonia is the main complication associated with a poor outcome; however, our analysis showed no significant differences in pneumonia rates between patients with versus without dysphagia. Thus, some other factors might determine the development of dysphagia in neurological patients. As demonstrated in our study, dysphagia was associated with the presence of structural brain lesions, which could be attributed to complexity of the swallowing process. It is controlled and regulated by complex supra-medullary networks, so brain lesions causing relevant swallowing-dysfunction seem to be an appropriate finding [18, 19].

In only 33.1% of the investigated patients, the initial diet regime was confirmed/maintained after performance of FEES. Despite extensive clinical expertise, the established diagnosis regarding

swallowing function was incorrect in nearly every second patient; 10.8% of patients had full oral intake although they would have needed a restriction. Low awareness of dysphagia, the inability of clinical examination and screening tests to detect silent aspirations or methodological reasons might also explain this result [2, 20]. Therefore, our results underline the necessity of performing elaborate dysphagia diagnostics on a routine basis and it supports recent trends implementing FEES examination as a standard procedure in severely affected neurological patients.

A restriction in oral diet was indicated more often in older patients. The physiological function decline, also called “presbyphagia” might be responsible for this observation [21]. Since the vast majority of neurological patients in general are of advanced age, these factors need to be taken into consideration when interpreting FEES findings. A structural brain lesion in addition to pre-existing presbyphagia might explain the pronounced severity of dysphagia in our study group. Mortality and pneumonia rate was higher in patients that had no change in oral diet. This might sound surprising at first, but this group included, apart from non-dysphagic patients, patients that were on a restricted diet or NPO based on the results of the BSE, CSE or clinical judgement. The group of NPO-patients had severe dysphagia and a proportion aspirated saliva, which might explain the higher rate of pneumonia and mortality. Those complications might have been prevented by intubation or tracheotomy, but in most patients, this was not an option for the patient or the treating physician. Again, this demonstrates the low awareness for dysphagia.

The selection bias considering a large number of intensive care patients must be taken into account when interpreting our results. Since those patients are more severely affected, i.e. by stroke, our findings could have overestimated the number of neurological patients affected by dysphagia, which might also explain the high frequency of pneumonia as compared to other researchers [22]. Because of ethical reasons, no control group (without FEES) was used/implemented: the risk of pneumonia and pneumonia-related death was considered too high. These are the main limitations of the study. However, the study design represents the clinical routine with a pre-selection of patients by using a

BSE or CSE followed by instrumented diagnostics. So far only one study by Bax and co-workers was published on the effect of FEES on outcome in 220 neurological patients [23]. However, in this study only some patients underwent FEES. Whereas in our study, all 241 patients underwent FEES procedure.

Conclusions

Implementing FEES, we could detect signs of dysphagia in 68.9% of our neurological patients. Dysphagia was associated with the presence of structural brain lesions, higher mortality and longer duration of hospitalization. A change of oral diet was associated with a lower incidence of pneumonia and lower mortality. Due to our findings only 33.1% of the patients had adequate oral diet. As most screening tests for dysphagia do not cover non-stroke patients and cannot detect silent aspiration, using FEES at low-threshold in all neurological patients might help identifying patients at risk with this safe and fast bed-side assessment tool. It ensures safety when deciding on the type of oral intake and brings the benefit of a marked reduction in mortality and morbidity.

Figures

Figure 1 – Disease entities detected in patients in percentage and absolute

Figure 2 – Strobe diagram of screening process and decisions after FEES

Appendices

Appendix 1 - Functional oral intake scale [13]

Appendix 2- FEDSS-Score [14]

List of abbreviations

BSE	bedside screening examination
CSE	comprehensive swallowing examination (CSE)
CT	computed tomography
FEDSS	fiber endoscopic dysphagia severity scale.
FEES	flexible endoscopic evaluation of swallowing
FOIS	functional oral intake scale
GUSS	Gugging Swallowing Screen
IQR	interquartile range
MRI	magnet resonance imaging
NPO	nil per os (no oral intake)
PEG	percutaneous endoscopic gastrostomy tube
SLT	speech and language therapist
VFSS	videofluoroscopic swallowing study

Declarations

Ethics approval and consent to participate: For the data acquisition and using them for scientific analyses an ethical approval was obtained from the local ethical committee (Justus-Liebig university, protocol number 208/16).

Consent for publication: Not applicable.

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Data sharing statement: The authors declare that the data supporting the findings of this study are available within the article. The data that support the findings of this study are not publically available due to local medical data protection policies.

Authors contributions: Conceptualisation: TB, MJ, MK, CT. FEES examinations: TB, MV, MM, IR. Analysed the data and statistics: TB, MJ, MP. Writing–original draft preparation: TB and CT. Writing–review and editing: TB, MJ, MV, MM, SF, IR, MK, MP, CT. ICMJE criteria for authorship read: TB, MJ, MV, MM, SF, IR, MK, MP, CT. Agree with manuscript results and conclusions: TB, MJ, MV, MM, SF, IR, MK, MP, CT.

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Table 1. Baseline characteristics in neurological patients and differences in patients with and without dysphagia

	Total cohort (n=241)	Normal swallowing function (n=75)	Relevant dysphagia (n=166)	*P*
Sex (number of male patients)	140 (58.1%)	41 (54.6%)	99 (59.6%)	0.401
Age (median, IQR)	73 (61-80)	71.5 (59-79.5)	73 (62-81)	0.261
Ischaemic stroke	125 (51.9%)	34 (45.3%)	91 (57.8%)	0.165
Intensive care unit	109 (45.2%)	34 (45.3%)	75 (45.2%)	>0.999
Brain lesion	187 (77.6 %)	49 (65.3%)	138 (83.1%)	**0.001**
Pneumonia	98 (40.7%)	28 (37.3%)	70 (42.2%)	0.481
Length of stay in hospital in days (median, IQR)	17 (11-29)	15 (9.75-22.75)	18 (12-30)	**0.005**
Death	15 (6.2%)	1 (1.3%)	14 (8.4%)	**0.041**
Change in oral diet	176 (65.9%)	61 (75.3%)	115 (61.8%)	0.36
Restriction	70 (26.2%)	2 (2.5%)	68 (36.6%)	**<0.001**
NPO started	47 (17.6%)	0 (0%)	47 (25.3%)	
De-escalation	106 (39.7%)	59 (72.8%)	47 (25.3%)	**<0.001**
PEG on admission	7 (2.9%)	3 (4%)	4 (2.4%)	0.682
PEG procedure in hospital	49 (20.3%)	14 (18.7%)	35 (21.1%)	0.731
PEG at discharge	54 (22.4%)	17 (22.7%)	37 (22.3%)	>0.999

IQR refers to interquartile range

NPO refers to nil per os (no oral intake)

PEG refers to percutaneous endoscopic gastrostomy tube

Table 2. Baseline characteristics in neurological patients and differences in patients with and without change in oral diet

	Total cohort (n=241)	No change in oral diet (n=80)	Change in oral diet (n=161)	*P*
Sex (number of male patients)	140 (58.1%)	45 (56.3%)	95 (59%)	0.782
Age (median, IQR)	73 (61-80)	74.5 (60.25-80.75)	72 (61-80)	0.286
Ischaemic stroke	125 (51.9%)	38 (47.5%)	87 (54%)	0.412
Intensive care unit	109 (45.2%)	43 (53.8%)	66 (41%)	**0.074**
Brain lesion	187 (77.6 %)	60 (75%)	127 (78.9)	0.515
Pneumonia	98 (40.7%)	40 (50%)	58 (36%)	0.051
Length of stay in hospital in days (median, IQR)	17 (11-29)	17.5 (12-33)	17 (11-26)	0.242
Death	15 (6.2%)	9 (11.3%)	6 (3.7%)	**0.043**
PEG on admission	7 (2.9%)	5 (6.3%)	2 (1.2%)	**0.042**
PEG procedure in hospital	49 (20.3%)	17 (21.3%)	32 (19.9%)	0.865
PEG at discharge	54 (22.4%)	20 (25%)	34 (21.1%)	0.515

IQR refers to interquartile range

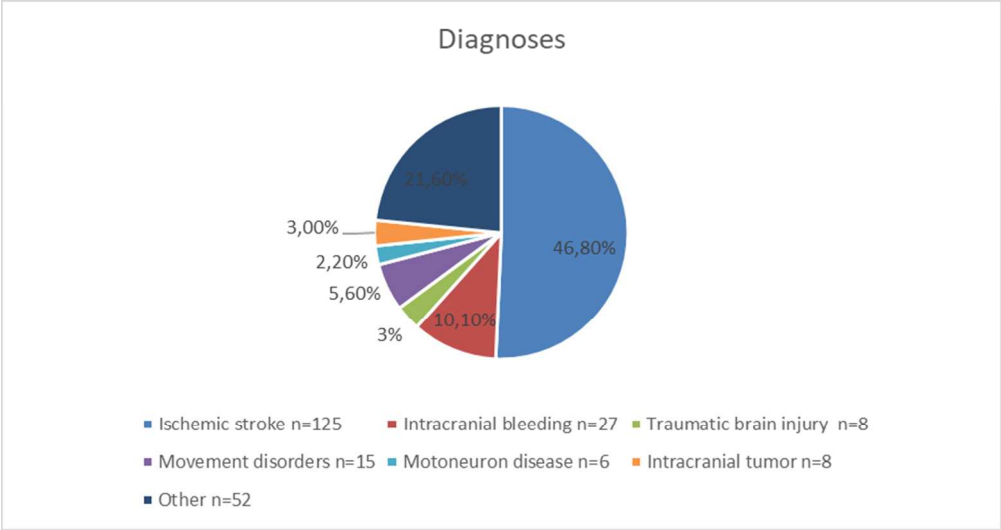
PEG refers to percutaneous endoscopic gastrostomy tube

Table 3. Differences in patients with de-escalation or restriction of oral diet

	Change in oral diet (n=161)	De-escalation of oral diet (n=93)	Restriction of oral diet (n=68)	*P*
Sex (number of male patients)	95 (59%)	55 (59.1%)	40 (58.8%)	>0.999
Age (median, IQR)	72 (61-80)	72 (60-79)	75 (66.25-82)	**0.01**
Ischaemic stroke	87 (54%)	43 (46.2%)	44 (64.7%)	**0.025**
Intensive care unit	66 (41%)	49 (52.7%)	17 (25%)	**0.001**
Brain lesion	127 (78.9)	68 (73.1%)	59 (86.8%)	**0.05**
Pneumonia	58 (36%)	38 (40.9%)	20 (29.4%)	0.183
Length of stay in hospital in days (median, IQR)	17 (11-26)	17 (11.75-27.25)	18 (11-31)	0.95
Death	6 (3.7%)	1 (1.1%)	5 (7.4%)	0.082
PEG on admission	2 (1.2%)	2 (2.2%)	0	
PEG procedure in hospital	32 (19.9%)	19 (20.4%)	13 (19.1%)	>0.999
PEG at discharge	34 (21.1%)	21 (22.6%)	13 (19.1%)	0.697

IQR refers to interquartile range

PEG refers to percutaneous endoscopic gastrostomy tube



Disease entities detected in patients in percentage and absolute

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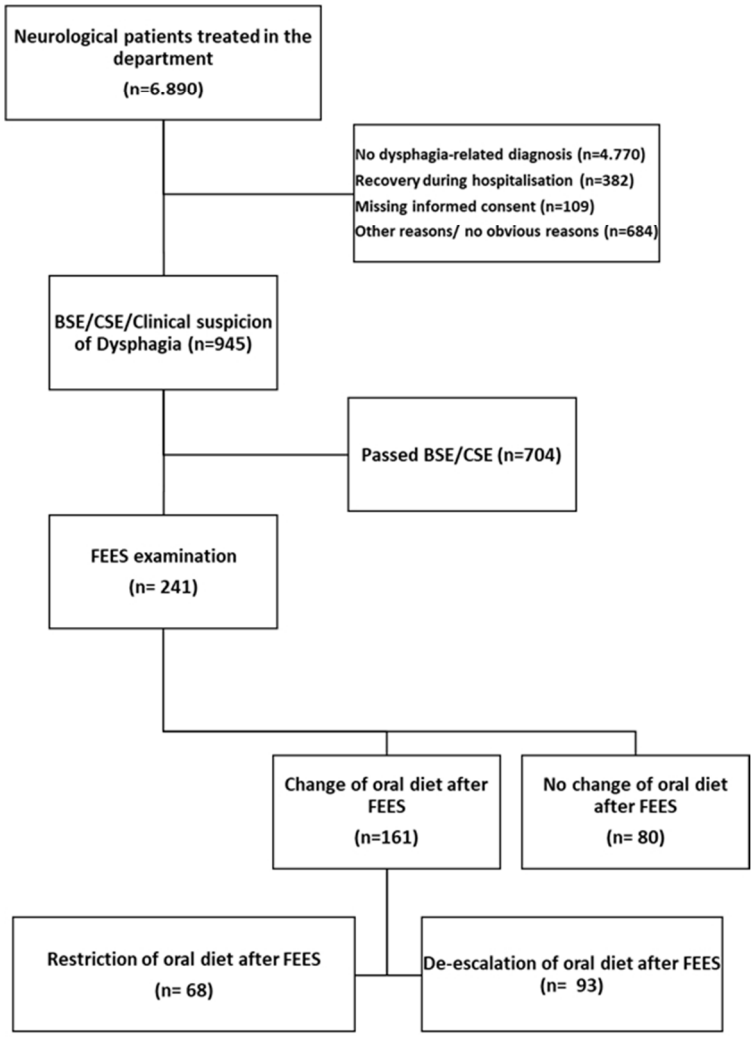

Strobe diagram of screening process and decisions after FEES

50x80mm (300 x 300 DPI)

1	Nothing by mouth (NPO)
2	Tube dependent with minimal attempts of food or liquid
3	Tube dependent with consistent oral intake of food or liquid
4	Total oral diet of a single consistency
5	Total oral diet with multiple consistencies, but requiring special preparation or compensations
6	Total oral diet with multiple consistencies without special preparation, but with specific food limitations
7	Total oral diet with no restrictions

Score		Main findings
6	Handling of secretions/Saliva	Penetration or Aspiration
5	Puree consistency	Penetration/Aspiration without or insufficient protective reflex
4		Penetration/Aspiration with sufficient protective reflex
4	Liquids	Penetration/Aspiration without or insufficient protective reflex
3		Penetration/Aspiration with sufficient protective reflex
2	Soft solid food	Penetration/Aspiration or massive residues in valleculae or pyriforms
1		No penetration/aspiration and not more than mild to moderate residues in valleculae or pyriforms

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What is the value of Flexible endoscopic evaluation of swallowing (FEES) in neurological patients? A cross-sectional hospital-based registry study.

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What is the value of Flexible endoscopic evaluation of swallowing (FEES) in neurological patients?

A cross-sectional hospital-based registry study

Tobias Braun*, MD[1]; Martin Juenemann, MD, M.Sc[1]; Maxime Viard, MD[1]; Meyer, Marco, MD[1]; Fuest, Sven, MD[1]; Iris Reuter, MD, PhD [1]; Manfred Kaps, MD, PhD[1], Mario Prosiegel, MD[2]; Christian Tanislav, MD[1]

Authors' affiliations:

[1] Department of Neurology, University Hospital Giessen and Marburg, Klinikstrasse 33, 35392 Giessen, Germany.

[2] Institute of German Linguistics, Lecturer for postgraduate master's speech therapy degrees, Schellingstr. 3, Ludwig-Maximilians-University, 80802 Munich, Germany.

***Corresponding Author:** Tobias Braun, Department of Neurology, University hospital Giessen und Marburg, Klinikstrasse 33, 35392 Giessen, Germany, tel. +49-641-985-56827, fax +49-641-985-45301, tobias.braun@neuro.med.uni-giessen.de

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Abstract

Objectives: Fiberendoscopic evaluation of swallowing (FEES) to detect dysphagia is gaining more and more importance as a diagnostic tool. Therefore, we have investigated the impact of FEES in neurological patients in a clinical setting.

Design: Cross-sectional hospital-based registry

Setting: Primary acute care in a neurological department of a German university hospital.

Participants: 241 patients with various neurological diseases who underwent FEES-procedure.

Primary and secondary outcome measures: Dysphagia and related comorbidities.

Results: 267 FEES were performed in 241 patients with various neurological diagnoses. Dysphagia was diagnosed in 68.9% of the patients. In only 33.1% of the patients appropriate oral diet was chosen prior to FEES. A relevant dysphagia occurred more often in patients with structural brain lesions (83.1% vs. 65.3%, p=0.001), dysphagic patients had a longer hospitalisation (median 18 [IQR 12-30] vs. 15 days [IQR 9.75-22.75], p=0.005) and had a higher mortality (8.4% vs. 1.3%, p=0.041). When the oral diet was changed, we observed a lower pneumonia rate (36% vs. 50%, p=0.051) and a lower mortality (3.7% vs 11.3%, p=0.043) in comparison to no change of oral diet. A restriction of oral diet was identified more often in older patients (median: 75 years [IQR 66.3-82 years] versus median 72 years [IQR 60-79 years); p=0.01) and in patients with structural brain lesions (86.8% vs. 73.1%; p=0.05).

Conclusion: On clinical investigation, dysphagia was misjudged for the majority of the patients. FEES might help to compensate this drawback, revising the diet regime in nearly 70 % of the patients.

Trial registration: Study was not registered.

Strengths and limitations:

- Performance of FEES by experienced examiners in a standardised manner

- Considering the current literature, our study has included the highest number (n=241) of neurological patients systematically examined with FEES
- Single centre study, which might lead to a centre-specific bias in diagnostic and therapeutic measures, influencing data-acquisition.

Background

Dysphagia is a common complication in neurological diseases with aspiration pneumonia as a leading cause of death in stroke, multiple sclerosis, amyotrophic lateral sclerosis, Parkinson disease or dementia [1–5]. In elderly patients suffering from infections, a concomitant aspiration pneumonia results in increased morbidity and mortality [6, 7]. Dysphagia determines therefore the immediate prognosis of ill patients, and due to the functional link to the central and peripheral nerve system, it is of particular relevance to neurological patients [7].

Apart from a physical examination performed by physicians or speech and language therapists, diagnostic tools have been developed to investigate the swallowing function [8]. Two procedures, the videofluoroscopic evaluation of swallowing (VFSS) and the fiberendoscopic evaluation of swallowing (FEES) have entered the clinical practice for this purpose. The latter works without radiation exposure and it can be easily repeated; it can be performed at bedside and even in uncooperative or unconscious patients. FEES is therefore gaining more and more importance in the examination of neurological patients [9, 10]. However, systematic studies providing the overall benefit of this procedure in neurological patients are currently missing.

Therefore, the aim of the presented study is to assess the value of FEES for unselected neurological patients regarding the benefit of judging the swallowing function and the related short-term outcome.

Methods

FEES has been performed in stroke patients with pathological bedside screening examination (BSE). In patients with other aetiologies, it has been performed when there were pathological findings in the comprehensive swallowing examination (CSE) conducted by a speech and language therapist (SLT). An indication for CSE was a clinical suspicion of dysphagia, i.e. in patients with newly diagnosed motor neuron disease or in those showing clinical signs of dysphagia (e.g. wet voice and/or coughing when drinking, etc.). In our department, we use the Gugging Swallowing Screen (GUSS) as a BSE for stroke-associated dysphagia. The GUSS consists of 4 subtests. In the first subtest, vigilance, the ability to

cough and swallowing of saliva are assessed. The next three steps evaluate the patient's ability to safely swallow semi-solid, liquid and solid food. In each subtest, a maximum of 5 points can be reached. The level of points determines the patient's severity of dysphagia. Due to the degree of severity, different diet recommendations are given [11]. The screening process is depicted in **Figure 1**. The oral diet prior to FEES was chosen by the attending physician and a SLT based on the findings in the CSE. In stroke patients, oral diet was chosen according to the instructions of the GUSS. For quality control reasons, findings gathered in examinations were documented systematically. All FEES procedures were performed in a standardized manner by experienced physicians (see below).

Patients

All patients treated in our department from January 2014 to September 2016 who underwent FEES were considered for the analysis. The data documented in the database included: age, sex, length of stay in hospital, diagnosis, presence of brain lesions (such as a new or old ischemic stroke, an intracerebral bleeding, a tumour, a cerebral atrophy, etc.), occurrence of pneumonia (defined as a clinical diagnosis of pneumonia; determined by the treating physician), treatment in the intensive care unit, mortality, presence of dysphagia and type of oral intake (before and after FEES). In order tp acquire data and to use them for scientific analyses, an ethical approval was obtained from the local ethical committee (Justus-Liebig-University, Giessen; protocol number 208/16).

FEES – Flexible endoscopic evaluation of swallowing

FEES is a videoendoscopic nasolaryngeal swallowing study. We performed FEES following the standardised FEES® protocol according to Langmore [12]: A small endoscope (about 4 mm in diameter) was introduced through the inferior nasal meatus and the epipharynx in the mesopharynx. Swallowing of saliva and different consistencies of food and liquids, penetration, aspiration, localization and amount of residues as well as patients' reactions (such as coughing) were visualised and documented. By definition, penetration is entering of any material into the airway (above the level of the vocal folds), aspiration means entering of any material below the level of the vocal folds. In the first step of the procedure, anatomical changes, management of saliva and movements of

swallowing related structures were assessed. Then, we tested pudding-thick consistency (thickened water), normal water and solid food. All consistencies were applied three times. If one of the consistencies appeared unsafe, we left out the corresponding consistence. Based on the findings in FEES, the appropriate oral diet was chosen for the patients. All FEES procedures were performed or supervised by an experienced investigator.

Outcome measurements

Oral intake and the degree of dysphagia severity were measured by using the functional oral intake scale (FOIS) and the Fiberoptic Endoscopic Dysphagia Severity Score (FEDSS), respectively:

FOIS is a seven-tiered scale ranging from 1 = no oral intake at all (NPO= nil per os) to 7 = full oral intake without restrictions (**Appendix 1**) [13]. The data of the functional oral intake scale were categorised in either NPO (FOIS=1), partial oral intake (FOIS =2-6) or full oral intake (FOIS=7). De-escalation of the oral diet was defined as a positive change on the FOIS, whereas restriction of the oral diet was defined as a negative change.

In order to define the overall severity of dysphagia, we used the FEDSS-scale developed by Dziewas and co-workers [14]. The FEDSS (Fiber Endoscopic Dysphagia Severity Score) is a six-tiered scale originally designed to use for stroke patients (**Appendix 2**). All parameters are recorded in a standardised way.

In order to evaluate the value of performing FEES in neurological patients, the following parameters were correlated with baseline data and dependent factors:

- Dysphagia as defined by a FEDSS score of ≥ 2
- Oral intake status as calculated by the FOIS and its overall change and type of change after FEES

Statistical analyses

Absolute and relative frequencies were calculated based on cross-tables. For comparing relative a two-tailed Fisher's exact test was used. Continuous variables were analysed by calculating the median

value and the interquartile range (25%-percentile and 75%-percentile). Nonparametric data were analysed employing the Mann–Whitney U-test. All statistical analyses were performed with the SPSS, release version 22.0 (©SPSS, Inc., IBM Company, 2015, Chicago-IL).

Results

Patients' characteristics

267 FEES were performed in 241 patients. In 23 patients (9.5%), the procedure was repeated at least once. Among those patients, an improvement of dysphagia was noted in 12 cases (52.1%). The subsequent examination revealed an increased severity of dysphagia in one patient and in a second patient, previously diagnosed with no dysphagia, aspiration was detected during a repeated examination.

140 patients were male (52.4%), the median age was 73 years (IQR [interquartile range] 61-80 years). 109 patients (45.2%) were treated on the intensive care unit. In 46.8% of the patients, an ischemic stroke was diagnosed. The different disease entities detected in our patients are summarized in **Figure 2**. The group classified as "other" consisted of patients with heterogeneous diagnoses (epileptic seizures, dementia, Guillain Barré-syndrom, degenerative changes of the cervical spine, etc.).

194 patients (80,5%) had CT-imaging of the brain, 69 (28.6%) underwent MR-imaging. 48 patients (19.9%) had both, a CT and MRI-scan, whereas 22 (9.1) patients had no imaging at all. 187 patients had a brain lesion detected in CT-scan or MRI (8 tumours, 125 new ischemic lesions, 27 bleedings, 27 other lesions [old ischemic lesions, unspecific white matter lesions, cortical atrophy, etc.]). 98 patients (40.7%) developed pneumonia, 15 patients died during hospitalisation (6.2%). Initially, 140 patients (52.4%) had no oral intake (NPO), 58 patients (24.1%) had partial oral intake and 43 patients (16.1%) had full oral intake. 108 patients (44.8%) were dependent on a nasogastric feeding tube prior to FEES and 7 patients (2.9%) on a PEG (percutaneous endoscopic gastrostomy)-tube. Patients' characteristics are presented in **Table 1**.

No side effects, i.e. laryngospasm, syncope or non-self-limiting epistaxis occurred, 2 patients (0.8%) had mild epistaxis after FEES.

FEES Examination

The median overall FEDSS score of the entire study population was 4 (IQR 1-6). FEES revealed no sign of dysphagia (FEDSS=1) for 75 patients (31.1%), whereas dysphagia (FEDSS 2-6) was diagnosed in 166 persons (68.9%).

An oral diet was more often de-escalated in patients without dysphagia (72.8% vs. 25.3%, p<0.0001) and was more often restricted in patients with dysphagia patients with a normal swallowing function (2.5% vs. 36.6%, p<0.001). As for 26 patients (10.8%) with a full oral intake, FEES showed a critical dysphagia and as a result, the diet was revaluated. Out of these 26 patients, 16 (61.5%) had a partial oral intake and 38.5% patients had NPO after FEES. Changes in oral diet after FEES can be seen in **Figure 1**.

Patients with brain lesions were more often diagnosed with dysphagia (65.3% vs. 83.1%; p=0.001). Patients with dysphagia stayed longer in hospital (median 15 [IQR 9.75-22.75] vs. 18 [IQR12-30] days, p=0.005) and had a higher mortality (8.4% vs. 1.3%, p=0.041. Results are summarized in **Table 1**.

Differences between patients with a change in the oral diet

A total of 161 patients (66.8%) had a change in the oral diet, 93 of them (57.8%) were de-escalated and (42.2%) a restriction was necessary in 68 patients., NPO was recommended after the examination in 47 of those 68 patients restricted in the oral diet (69.1%). Patients without a change of the oral diet had a higher rate of pneumonia (40.4% vs. 36%, p=0.051) and a higher mortality as compared to those with a change in the oral diet (10% vs 3.7%, p=0.043). Results are summarized in **Table 2**.

Differences between patients with de-escalation and restriction of the oral diet

In the patients with a change in oral diet, a restriction of oral diet was indicated more often in older patients (median 75 [IQR 66.25-82] years old vs 72 [IQR 60-79) vs, p=0.01), in patients with an ischemic stroke (64.7% vs. 46.2%, p=0.025) or patients with any other brain lesion (86.8% vs. 73.1%,

p=0.05) as compared to de-escalation of oral diet. There was also a higher mortality in patients with restriction in oral diet as compared to de-escalation (7.4% vs. 1.1%, *p*=0.082). Results are summarized in **Table 3**.

Discussion

FEES showed relevant dysphagia in 166 (68.9%) of 241 unselected neurological patients. After performing the FEES, the diet was revised in 66.8% of the patients. A restriction of oral intake was indicated for predominantly elderly patients and those suffering from stroke or those with other structural brain lesions. Relevant dysphagia was associated with a higher mortality and a longer duration of hospitalization.

Different studies identified dysphagia as a strong factor associated with the bad outcome in many disorders [1–5, 15–17]. Therefore, establishing the right diagnosis with initiatiatin the appropriate therapeutic measures is of major relevance. In this context, FEES seems to be a promising tool of identifying patients at risk. With this procedure, a considerable number of patients with relevant dysphagia resulting in the immediate adjustment of the oral diet could be identified. In line with investigations in other populations, patients diagnosed with dysphagia in our study had a longer period of hospitalisation and a higher risk for poor outcome. It can be expected that pneumonia is the main complication associated of a poor outcome; however, our analysis showed no significant differences in pneumonia rates between patients with compared to patients without dysphagia. Thus, some other factors might determine the development of dysphagia in neurological patients. As demonstrated in our study, dysphagia was associated with the presence of structural brain lesions, which could be attributed to the complexity of the swallowing process. Swallowing is controlled and regulated by complex supra-medullary networks, so brain lesions causing a relevant swallowing-dysfunction seem to be an appropriate finding [18, 19].

The initial diet regime was maintained after performance of FEES for only 33.1% of the investigated patients. Despite extensive clinical expertise, the established diagnosis regarding the swallowing function was incorrect in nearly every second patient; 10.8% of the patients had full oral intake although they would have needed a restriction. A lack of awareness of dysphagia, the inability of clinical examinations and screening tests in ordert to detect silent aspirations or methodological reasons might also explain this result [2, 20]. Therefore, our results underline the necessity of performing elaborate dysphagia diagnostics on a routine basis and they support recent trends implementing FEES examination as a standard procedure in severely affected neurological patients.

A restriction of an oral diet was indicated more often in older patients. The age related impairment of physiological function, also called “presbyphagia” might be responsible for this observation [21]. Since the vast majority of neurological patients in general are of an advanced age, presbyphagia needs to be taken into consideration when interpreting FEES findings. A structural brain lesion in addition to pre-existing presbyphagia might explain the distinct severity of dysphagia in our study group. Mortality and pneumonia rate were higher in patients that had no change of their oral diet. This might sound surprising at first, but this group included, apart from non-dysphagic patients, patients that were on a restricted diet or NPO based on the results of the BSE, CSE or clinical judgement. The group of NPO-patients had severe dysphagia and a group of them aspirated saliva, which might explain the higher rate of pneumonia and mortality. Those complications might have been prevented by intubation or tracheotomy, but for most patients, this was not an option for the patient or the treating physician. Again, this demonstrates the lack of awareness for dysphagia.

A selection bias considering a large number of intensive care patients must be taken into account when interpreting our results. Since those patients are more severely affected, i.e. by stroke, our findings could have overestimated the number of neurological patients affected by dysphagia, which might also explain the high frequency of pneumonia as compared to other researchers [22]. Because of ethical reasons, no control group (without FEES) was set up: the risk of pneumonia and

pneumonia-related death was considered too high. These are the main limitations of the study. However, the study design represents the clinical routine with a pre-selection of patients by using a BSE or CSE followed by instrumented diagnostics. So far only one study by Bax and co-workers has been published about the effect of FEES on the outcome in 220 neurological patients [23]. However, in this study only some patients underwent FEES. Whereas in our study, all 241 patients underwent FEES procedure.

Conclusions

By implementing FEES, we could detect signs of dysphagia in 68.9% of our neurological patients. Dysphagia was associated with the presence of a structural brain lesions, a higher mortality and a longer duration of hospitalization. A change of the oral diet was associated with a lower incidence of pneumonia and a lower mortality. Due to our findings only 33.1% of the patients had an adequate oral diet. As most screening tests for dysphagia do not cover non-stroke patients and cannot detect silent aspiration, using FEES at a low threshold for all neurological patients might help identifying patients at risk with this safe and fast bed-side assessment tool. It ensures safety when deciding on the type of the oral intake and brings the benefit of a marked reduction in mortality and morbidity.

Figures

Figure 1 – Strobe diagram of screening process and decisions after FEES

Figure 2 – Disease entities detected in patients in percentage and absolute

Appendices

Appendix 1 - Functional oral intake scale [13]

Appendix 2- FEDSS-Score [14]

List of abbreviations

BSE	bedside screening examination
CSE	comprehensive swallowing examination (CSE)
CT	computed tomography
FEDSS	fiber endoscopic dysphagia severity scale.
FEES	flexible endoscopic evaluation of swallowing
FOIS	functional oral intake scale
GUSS	Gugging Swallowing Screen
IQR	interquartile range
MRI	magnet resonance imaging
NPO	nil per os (no oral intake)
PEG	percutaneous endoscopic gastrostomy tube
SLT	speech and language therapist
VFSS	videofluoroscopic swallowing study

Declarations

Ethics approval and consent to participate: For the data acquisition and the use of them for scientific analyses an ethical approval was obtained from the local ethical committee (Justus-Liebig university, protocol number 208/16).

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Authors contributions: Conceptualisation: TB, MJ, MK, CT. FEES examinations: TB, MV, MM, IR. Analysed the data and statistics: TB, MJ, MP. Writing–original draft preparation: TB and CT. Writing–review and editing: TB, MJ, MV, MM, SF, IR, MK, MP, CT. ICMJE criteria for authorship read: TB, MJ, MV, MM, SF, IR, MK, MP, CT. Agree with manuscript results and conclusions: TB, MJ, MV, MM, SF, IR, MK, MP, CT.

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Table 1. Baseline characteristics of neurological patients and differences in patients with and without dysphagia

	Total cohort (n=241)	Normal swallowing function (n=75)	Relevant dysphagia (n=166)	*P*
Sex (number of male patients)	140 (58.1%)	41 (54.6%)	99 (59.6%)	0.401
Age (median, IQR)	73 (61-80)	71.5 (59-79.5)	73 (62-81)	0.261
Ischaemic stroke	125 (51.9%)	34 (45.3%)	91 (57.8%)	0.165
Intensive care unit	109 (45.2%)	34 (45.3%)	75 (45.2%)	>0.999
Brain lesion	187 (77.6 %)	49 (65.3%)	138 (83.1%)	**0.001**
Pneumonia	98 (40.7%)	28 (37.3%)	70 (42.2%)	0.481
Length of stay in hospital in days (median, IQR)	17 (11-29)	15 (9.75-22.75)	18 (12-30)	**0.005**
Death	15 (6.2%)	1 (1.3%)	14 (8.4%)	**0.041**
Change in oral diet	176 (65.9%)	61 (75.3%)	115 (61.8%)	0.36
Restriction	70 (26.2%)	2 (2.5%)	68 (36.6%)	**<0.001**
NPO started	47 (17.6%)	0 (0%)	47 (25.3%)	
De-escalation	106 (39.7%)	59 (72.8%)	47 (25.3%)	**<0.001**
PEG on admission	7 (2.9%)	3 (4%)	4 (2.4%)	0.682
PEG procedure in hospital	49 (20.3%)	14 (18.7%)	35 (21.1%)	0.731
PEG at discharge	54 (22.4%)	17 (22.7%)	37 (22.3%)	>0.999

IQR refers to interquartile range

NPO refers to nil per os (no oral intake)

PEG refers to percutaneous endoscopic gastrostomy tube

Table 2. Baseline characteristics of neurological patients and differences of patients with and without a change of the oral diet

	Total cohort (n=241)	No change in oral diet (n=80)	Change in oral diet (n=161)	*P*
Sex (number of male patients)	140 (58.1%)	45 (56.3%)	95 (59%)	0.782
Age (median, IQR)	73 (61-80)	74.5 (60.25-80.75)	72 (61-80)	0.286
Ischaemic stroke	125 (51.9%)	38 (47.5%)	87 (54%)	0.412
Intensive care unit	109 (45.2%)	43 (53.8%)	66 (41%)	**0.074**
Brain lesion	187 (77.6 %)	60 (75%)	127 (78.9)	0.515
Pneumonia	98 (40.7%)	40 (50%)	58 (36%)	0.051
Length of stay in hospital in days (median, IQR)	17 (11-29)	17.5 (12-33)	17 (11-26)	0.242
Death	15 (6.2%)	9 (11.3%)	6 (3.7%)	**0.043**
PEG on admission	7 (2.9%)	5 (6.3%)	2 (1.2%)	**0.042**
PEG procedure in hospital	49 (20.3%)	17 (21.3%)	32 (19.9%)	0.865
PEG at discharge	54 (22.4%)	20 (25%)	34 (21.1%)	0.515

IQR refers to interquartile range

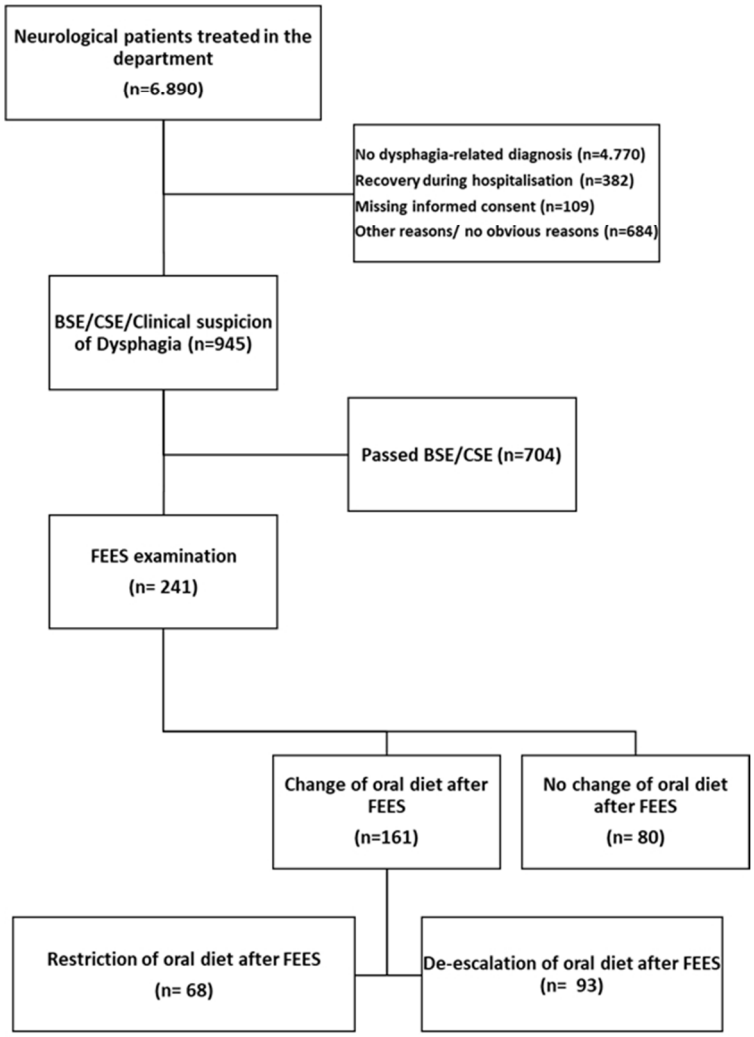
PEG refers to percutaneous endoscopic gastrostomy tube

Table 3. Differences of patients with de-escalation or restriction of the oral diet

	Change in oral diet (n=161)	De-escalation of oral diet (n=93)	Restriction of oral diet (n=68)	*P*
Sex (number of male patients)	95 (59%)	55 (59.1%)	40 (58.8%)	>0.999
Age (median, IQR)	72 (61-80)	72 (60-79)	75 (66.25-82)	**0.01**
Ischaemic stroke	87 (54%)	43 (46.2%)	44 (64.7%)	**0.025**
Intensive care unit	66 (41%)	49 (52.7%)	17 (25%)	**0.001**
Brain lesion	127 (78.9)	68 (73.1%)	59 (86.8%)	**0.05**
Pneumonia	58 (36%)	38 (40.9%)	20 (29.4%)	0.183
Length of stay in hospital in days (median, IQR)	17 (11-26)	17 (11.75-27.25)	18 (11-31)	0.95
Death	6 (3.7%)	1 (1.1%)	5 (7.4%)	0.082
PEG on admission	2 (1.2%)	2 (2.2%)	0	
PEG procedure in hospital	32 (19.9%)	19 (20.4%)	13 (19.1%)	>0.999
PEG at discharge	34 (21.1%)	21 (22.6%)	13 (19.1%)	0.697

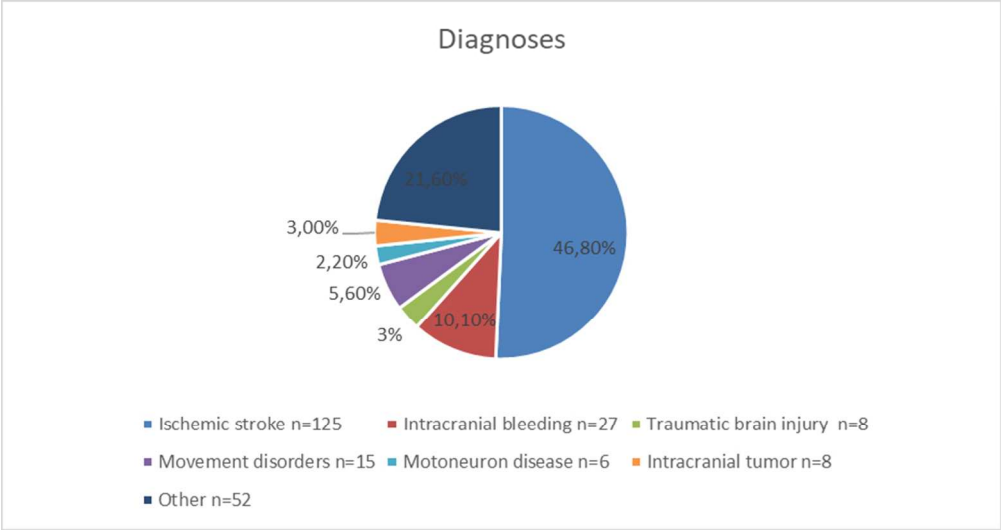
IQR refers to interquartile range

PEG refers to percutaneous endoscopic gastrostomy tube



Strobe diagram of screening process and decisions after FEES

50x80mm (300 x 300 DPI)



Disease entities detected in patients in percentage and absolute

78x41mm (300 x 300 DPI)

1	Nothing by mouth (NPO)
2	Tube dependent with minimal attempts of food or liquid
3	Tube dependent with consistent oral intake of food or liquid
4	Total oral diet of a single consistency
5	Total oral diet with multiple consistencies, but requiring special preparation or compensations
6	Total oral diet with multiple consistencies without special preparation, but with specific food limitations
7	Total oral diet with no restrictions

Score		Main findings
6	Handling of secretions/Saliva	Penetration or Aspiration
5	Puree consistency	Penetration/Aspiration without or insufficient protective reflex
4		Penetration/Aspiration with sufficient protective reflex
4	Liquids	Penetration/Aspiration without or insufficient protective reflex
3		Penetration/Aspiration with sufficient protective reflex
2	Soft solid food	Penetration/Aspiration or massive residues in valleculae or pyriforms
1		No penetration/aspiration and not more than mild to moderate residues in valleculae or pyriforms

STROBE Statement—Checklist of items that should be included in reports of ***cross-sectional studies***

	Item No	Recommendation
Title and abstract	1	(*a*) Indicate the study's design with a commonly used term in the title or the abstract ↑1
		(*b*) Provide in the abstract an informative and balanced summary of what was done and what was found ↑2
Introduction		
Background/rationale	2	Explain the scientific background and rationale for the investigation being reported ↑4
Objectives	3	State specific objectives, including any prespecified hypotheses ↑4
Methods		
Study design	4	Present key elements of study design early in the paper ↑4
Setting	5	Describe the setting, locations, and relevant dates, including periods of recruitment, exposure, follow-up, and data collection ↑4
Participants	6	(*a*) Give the eligibility criteria, and the sources and methods of selection of participants ↑5
Variables	7	Clearly define all outcomes, exposures, predictors, potential confounders, and effect modifiers. Give diagnostic criteria, if applicable ↑6
Data sources/ measurement	8*	For each variable of interest, give sources of data and details of methods of assessment (measurement). Describe comparability of assessment methods if there is more than one group ↑6
Bias	9	Describe any efforts to address potential sources of bias ↑10/11
Study size	10	Explain how the study size was arrived at ↑5
Quantitative variables	11	Explain how quantitative variables were handled in the analyses. If applicable, describe which groupings were chosen and why ↑6/7
Statistical methods	12	(*a*) Describe all statistical methods, including those used to control for confounding ↑6/7
		(*b*) Describe any methods used to examine subgroups and interactions
		(*c*) Explain how missing data were addressed
		(*d*) If applicable, describe analytical methods taking account of sampling strategy
		(*e*) Describe any sensitivity analyses
Results		
Participants	13*	(a) Report numbers of individuals at each stage of study—eg numbers potentially eligible, examined for eligibility, confirmed eligible, included in the study, completing follow-up, and analysed ↑7
		(b) Give reasons for non-participation at each stage n/a
		(c) Consider use of a flow diagram → Fig. 1
Descriptive data	14*	(a) Give characteristics of study participants (eg demographic, clinical, social) and information on exposures and potential confounders ↑7 + Table 1
		(b) Indicate number of participants with missing data for each variable of interest n/a
Outcome data	15*	Report numbers of outcome events or summary measures ↑8 + Table 1,2,3
Main results	16	(*a*) Give unadjusted estimates and, if applicable, confounder-adjusted estimates and their precision (eg, 95% confidence interval). Make clear which confounders were adjusted for and why they were included n/a
		(*b*) Report category boundaries when continuous variables were categorized
		(*c*) If relevant, consider translating estimates of relative risk into absolute risk for a meaningful time period
Other analyses	17	Report other analyses done—eg analyses of subgroups and interactions, and sensitivity analyses n/a

Discussion			
Key results	18	Summarise key results with reference to study objectives	↑ 9/10
Limitations	19	Discuss limitations of the study, taking into account sources of potential bias or imprecision. Discuss both direction and magnitude of any potential bias	↑ 10/11
Interpretation	20	Give a cautious overall interpretation of results considering objectives, limitations, multiplicity of analyses, results from similar studies, and other relevant evidence	↑ 11
Generalisability	21	Discuss the generalisability (external validity) of the study results	↑ 11
Other information			
Funding	22	Give the source of funding and the role of the funders for the present study and, if applicable, for the original study on which the present article is based	↑ 13

*Give information separately for exposed and unexposed groups.

Note: An Explanation and Elaboration article discusses each checklist item and gives methodological background and published examples of transparent reporting. The STROBE checklist is best used in conjunction with this article (freely available on the Web sites of PLoS Medicine at http://www.plosmedicine.org/, Annals of Internal Medicine at http://www.annals.org/, and Epidemiology at http://www.epidem.com/). Information on the STROBE Initiative is available at www.strobe-statement.org.