ORIGINAL ARTICLE

Transesophageal Echocardiography – Dysphagia Risk in Acute Stroke (TEDRAS): a prospective, blind, randomized and controlled clinical trial

S. Hamzic[a,b], T. Braun[a,b], M. Butz[a,b], H. Khilan[a,c], S. Weber[c], M. Yeniguen[a,b], T. Gerriets[a,b,c], P. Schramm[b,d] and M. Juenemann[a,b]

[a]*Department of Neurology, University Hospital Giessen and Marburg GmbH, Justus-Liebig-University, Giessen;* [b]*Heart and Brain Research Group, Heart-, Lung-, Vascular- and Rheumatic Centre Bad Nauheim, Kerckhoff Clinic GmbH, Bad Nauheim;* [c]*Department of Neurology/Stroke Unit, Gesundheitszentrum Wetterau, Friedberg, Hesse; and* [d]*Department of Anaesthesiology, University Medical Centre of the Johannes Gutenberg-University, Mainz, Germany*

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Keywords:
dysphagia, dysphagia risk, FEES, stroke, transesophageal echocardiography

Received 22 May 2020

European Journal of Neurology 2021, **28:** 172–181

doi:10.1111/ene.14516

Background and purpose: Dysphagia is common in acute stroke and leads to worse overall outcome. Transesophageal echocardiography (TEE) is used in the diagnostic evaluation of stroke with regard to its etiology and is a known cause of postoperative dysphagia in cardiac surgery. The prevalence of dysphagia in acute stroke patients undergoing TEE remains unknown. The aim of the Transesophageal Echocardiography – Dysphagia Risk in Acute Stroke (TEDRAS) study was to assess the influence of TEE on swallowing among patients who have experienced acute stroke.

Methods: The TEDRAS study was a prospective, blind, randomized, controlled trial that included two groups of patients with acute stroke. Simple unrestricted randomization was performed, and examiners were blinded to each other's results. Swallowing was tested using flexible endoscopic evaluation of swallowing (FEES) at three different time points in the intervention group (24 h before, immediately after and 24 h after TEE) and in the control group (FEES on three consecutive days and TEE earliest after the third FEES). Validated scales were used to assess dysphagia severity for all time points as primary outcome measures.

Results: A total of 34 patients were randomized: 19 to the intervention group and 15 to the control group. The key findings of the repeated-measures between-group comparisons were significant increases in the intervention group for the following dysphagia measures: (1) secretion severity score (immediately after TEE: $P < 0.001$; 24 h after TEE: $P < 0.001$) and (2) Penetration-Aspiration Scale score for saliva (immediately after TEE: $P < 0.001$; 24 h after TEE: $P = 0.007$), for small (immediately after TEE: $P = 0.009$) and large liquid boli (immediately after TEE: $P = 0.009$; 24 h after TEE: $P = 0.025$).

Conclusion: The results indicate a negative influence of TEE on swallowing in acute stroke patients for at least 24 hours.

Introduction

The stroke incidence rate in Europe is reported to range from 95 to 290/100 000 per year [1]. In western countries, it is the third most common cause of death and the leading cause of disability among adults [2,3]. Dysphagia is a frequent complication of stroke, with a high variability of incidence among stroke survivors, ranging from 19% to 81% [4–7]. Dysphagia after stroke correlates with an increased risk of stroke-associated aspiration pneumonia (SAP) [8] and an

Correspondence: S. Hamzic, Department of Neurology, University Hospital Giessen and Marburg GmbH, Campus Giessen, Klinikstrasse 33, Giessen, Hesse, 35392, Germany (tel.: +49 641 985 59233; fax: +49 641 985 45309; e-mail: samra.hamzic@neuro.med.uni-giessen.de).

increased risk of mortality [9]. Early detection of dysphagia improves overall outcome and reduces mortality risk, risk of SAP, dehydration and malnutrition, and length of hospitalization and overall costs of treatment [10].

In German stroke units, speech and language therapists perform bedside, instrumental examination of swallowing via flexible endoscopic evaluation of swallowing (FEES) within 24 h of admission [11,12]. FEES is a simple, low-risk, time- and cost-effective diagnostic tool for the detection of dysphagia severity, pharyngeal residue and aspiration [13], allowing conclusions to be drawn about the involved pathological mechanisms of swallowing which serve as a basis for the selection of appropriate therapy [14].

Transesophageal echocardiography (TEE) is a routine examination to identify sources of cardiac embolism as possible stroke etiology. The risk of dysphagia after cardiac surgery associated with intra-operative implementation of TEE has been examined in only a few trials. Houge *et al*. found intra-operative implementation of TEE, besides age and duration of intubation, to be an independent predictor of postoperative dysphagia, with an incidence of 5.2% [15]. The odds ratio for dysphagia in patients who underwent intra-operative TEE was 7.8 times higher than in patients without intra-operative TEE in a case series by Rousous *et al*. [16]. The negative influence of long duration of intra-operative TEE probe placement in the esophagus on swallowing was confirmed in the prospective randomized trial by Chin *et al*. [17]. In this trial, the incidence of postoperative dysphagia for patients with a longer duration of intra-operative TEE probe placement in the esophagus was 51.1% compared to 28.6% for patients with a shorter duration of intra-operative TEE probe placement [17]. Grimm *et al*. [18] described pharyngeal residue, followed by laryngeal penetration and aspiration, as the most frequent symptoms of dysphagia after intra-operative TEE in cardiac patients, as diagnosed via videofluoroscopy. To date, no data are available on the incidence and severity of dysphagia after TEE in acute stroke patients.

In our clinical routine, we noted frequent reports of swallowing difficulties and/or clinical signs of swallowing impairment from our acute stroke patients who had undergone TEE. These reports are consistent with data from the above-mentioned studies on TEE in cardiac surgery. The present prospective, randomized, controlled and blinded study is the first to examine systematically the impact of TEE on swallowing among acute stroke patients, aiming to optimize acute stroke management by promptly detecting or preventing potential secondary risks of SAP in such patients. In clinical routine, swallowing difficulties and/or clinical signs of swallowing impairment are frequently reported in acute stroke patients who have undergone TEE. To date, however, this connection has not been scientifically investigated and evaluated.

Materials and methods

The TEDRAS study was conducted at the community hospital *Gesundheitszentrum Wetterau* (GZW) in Friedberg/Hesse (Germany). Procedures were carried out according to the Guidelines for Good Clinical Practice, the Federal Data Protecting Act and the Helsinki Declaration of the World Medical Association. The trial received ethical approval from the Research Ethics Committee at the Justus Liebig University in Giessen, Germany (AZ.: 223/12). Each patient or legal representative provided written informed consent. The study was initiated, designed and conducted by the investigator. All the data reside with the investigator. The TEDRAS study is registered in the ClinicalTrials.gov database under the ClinicalTrials.gov Identifier: NCT04302883.

The inclusion criteria were as follows: acute stroke (maximum 7 days post-onset), as displayed by cranial computed tomography or magnetic resonance imaging; written informed consent either from patients themselves or a legal representative; and indication for TEE.

Patients were excluded based on the following criteria: brain hemorrhage; either pre-existing neurogenic dysphagia or head-and-neck cancer-induced dysphagia; dementia; and aphasia with an impairment in language comprehension.

The TEDRAS study was a prospective, blind, randomized, controlled study (Fig. 1). Simple unrestricted randomization was performed according to a randomization list, concealed in sequentially numbered and sealed envelopes. The sealed envelopes were opened by a medical doctor before each inclusion to allocate patients to one of two groups: an intervention group, who underwent FEES on three consecutive days with TEE on the second day, or a control group, who underwent FEES on three consecutive days and a TEE after the third FEES (Fig. 2). The medical doctor responsible for the randomization was excluded from all following examinations. All examiners were blinded to each other's clinical and instrumental examination results. The study was unblinded for patients.

Within 24 h of admission to the stroke unit, all participants underwent a routine clinical swallowing

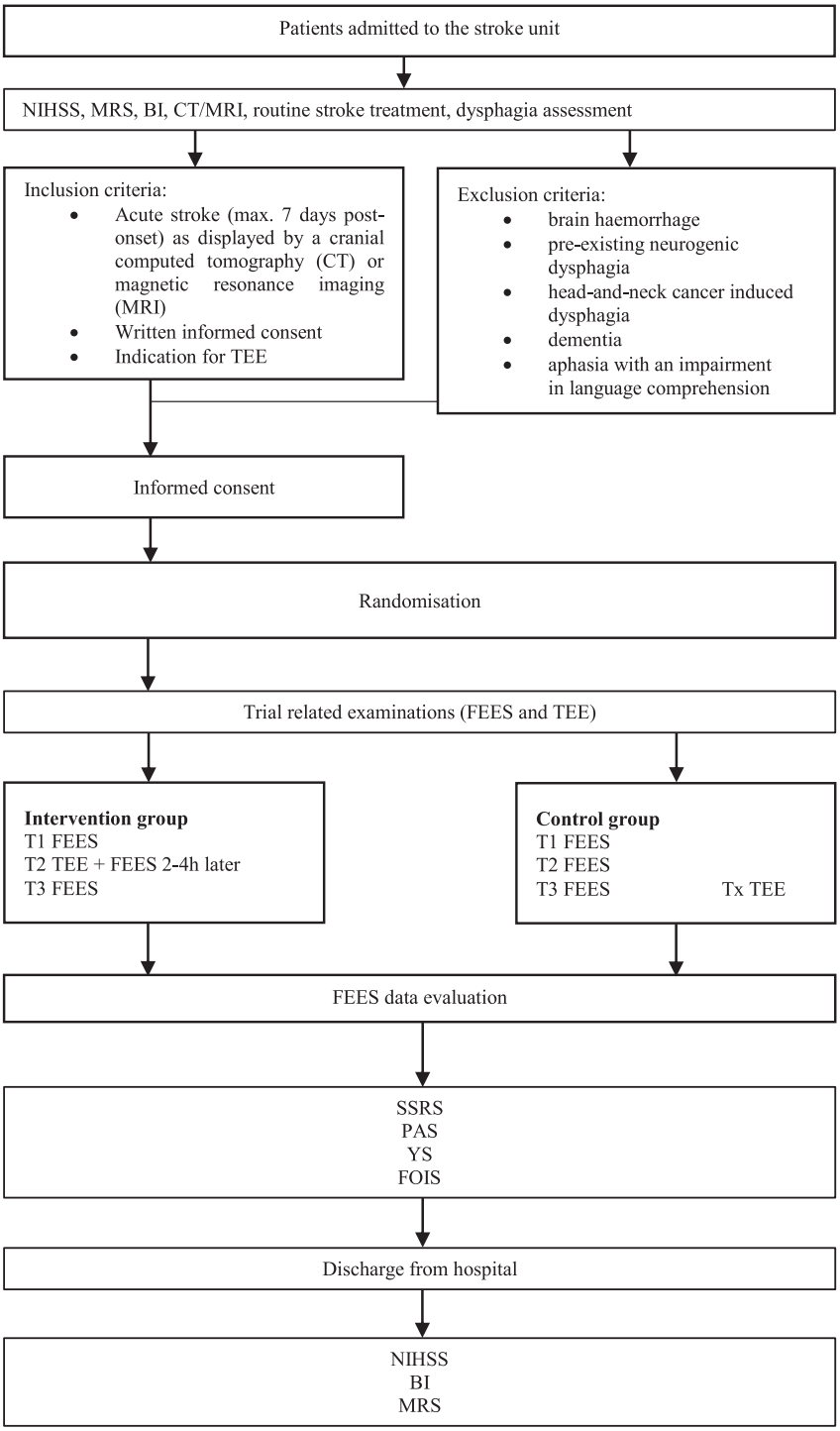

Figure 1 Graphic representation of the study design. BI, Barthel index; FEES, flexible endoscopic evaluation of swallowing; mRS, modified Rankin scale; FOIS, Functional Oral Intake Scale NIHSS, National Institutes Health Stroke Scale; PAS, Penetration Aspiration Scale; TEE, transesophageal echocardiography; SSRS, Secretion Severity Rating Scale; YS, Yale Pharyngeal Residue Severity Ratings Scale.

examination by a speech and language therapist. FEES examination was performed either by a doctor specialized in neurology or a speech and language therapist, both with more than 10 years' experience in performing FEES, and in FEES evaluation and research, and board-certified by the German Society

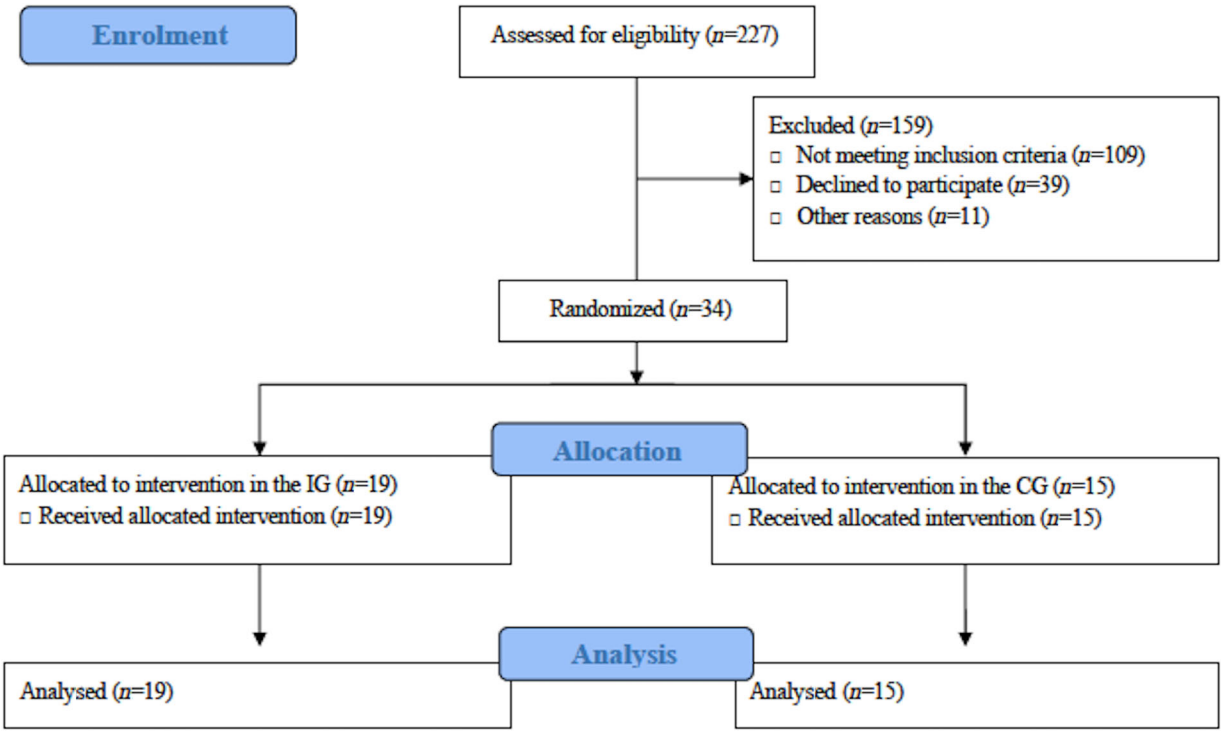

Figure 2 Patient recruitment flow diagram, detailing number of included, excluded and analysed participants. CG, control group; IG, intervention group. [Colour figure can be viewed at wileyonlinelibrary.com]

of Neurology. TEE was conducted by the Department of Internal Medicine at the GZW in Friedberg, independently of study participation.

Flexible endoscopic evaluation of swallowing

Equipment used for FEE at the GZW in Friedberg consisted of a Rehder/Partner Swallowing Workstation (Hamburg, Germany) with a Karl Storz 3.6-mm nasoendoscope and camera. Fiberendoscopic video sequences were captured using a digital picture archiving and communication system (Rehder/Partner). The rate of picture capture was 25 frames/s, and the frame size was 1021 × 1021 pixels.

Before the FEES, anti-congestive nose drops were used and the nostrils anesthetized by lidocaine, applied topically via cotton sticks.

During the FEES, a first evaluation of the patient's management of saliva was conducted. Subsequently, the patients were asked to swallow the following: three teaspoons of water; three sips of water; three teaspoons of apple sauce; and three morsels of crisp bread.

Dysphagia severity was measured using the three validated dysphagia scores described below. The inability to manage saliva and secretion correlates with a high risk of aspiration pneumonia and was therefore measured by the four-point Secretion Severity Rating Scale (SSRS) [19]. The Penetration-Aspiration Scale (PAS) measures the degree of penetration and aspiration of saliva, liquids and food on an eight-point scale, including description of the sensible reaction to penetration and/or aspiration and the ability to expectorate the penetrated and/or aspirated bolus [20]. The severity of hypopharyngeal residue of saliva, food and liquids was evaluated using the five-point Yale Pharyngeal Residue Severity Scale (YS) [21]. Higher SSRS, PAS and YS scores indicate higher risks of aspiration pneumonia. The range of oral intake of liquids and food after every FEES was measured using the seven-point Functional Oral Intake Scale (FOIS). Decreasing FOIS scores indicate a deterioration in oral intake, different ranges of non-oral feeding are included in levels 1–3 on this scale, whereas different ranges of oral feeding are included in levels 4–7 [22,23].

Flexible endoscopic evaluation of swallowing was aborted for any tested substance consistency in case of aspiration of saliva (PAS score >6) or aspiration of liquid, puree or solid boli during the examination (PAS score >6).

Flexible endoscopic evaluation of swallowing video sequences were randomized and pseudonymized by an independent examiner and subsequently presented to a neurology specialist with at least 5 years' experience in treatment of stroke patients and certified in FEES by the German Society of Neurology and the European Society for Swallowing Disorders. The neurology specialist was blinded to all previous results and assigned SSRS, PAS and YS scores to all consistencies applied in the swallowing evaluation.

Transesophageal echocardiography

The TEE equipment consisted of a VIVID S6 ultrasound workstation and GE Healthcare Type 6TC-RS probe (GE Healthcare, Chicago, IL, USA). The Department of Internal Medicine at the GZW in Friedberg conducted the TEE, independent of study participation. Anesthesia was administered either intravenously with propofol or by using a combination of intravenous anesthesia with propofol and local anesthesia of the pharynx using lidocaine spray. Oral intake of food and liquids was restricted at least 6 h before and until 24 h after the TEE.

Stroke outcome measures

Barthel index (BI), modified Rankin Scale (mRS) and National Institutes of Health Stroke Scale (NIHSS) scores were recorded for all patients [24–26].

Statistical methods

Baseline between-group comparison of age, and NIHSS, mRS and Barthel index scores were performed using a *t*-test for independent variables or, when appropriate, a Mann–Whitney *U*-test. Gender, localization of stroke, vascular territory and distribution of anesthesia were analysed using Pearson's chi-squared test or, when appropriate, Fischer's exact test.

To determine the influence of TEE, differences in scores were recorded from pre-intervention to immediately after intervention and 24 h post-intervention for all rating scale measures in both groups, using the Mann–Whitney *U*-test for between-group comparisons (interaction effect). To determine the frequency of aspiration we first dichotomized the PAS score using a cut-off value of 6 (PAS <6 = no aspiration; PAS ≥ 6 = aspiration), following the calculation of score differences between the test time points. These differences (increase and decrease in aspirations) were compared between the groups using Pearson's chi-squared test or, when appropriate, Fischer's exact test. Differences in scores between admission and discharge for the stroke outcome measures evaluated via the NIHSS, mRS, Barthel index and FOIS were calculated. Within-group comparisons were calculated using a Wilcoxon signed-rank test.

The statistical significance level was set at $P < 0.05$. Statistical analysis was carried out using Statistical Package for Social Science software 25.0 (SPSS, Chicago, IL, USA). Effect size calculation for non-parametric data was made using Cohen's r, where values >0.5 are interpreted as a large, values 0.3–0.5 as a medium and values 0.1–0.3 as a small effect size [27].

Sample size calculation

Since no preliminary results from the literature were available on which to base our sample size estimation for our outcomes, we decided to evaluate the supposed intervention effect exploratively in an interim analysis during the course of the study. For organizational and economic reasons, we used a sample size of 34 patients, as this seemed to be sufficient, for a first interim analysis. Once the effect size had been determined by the interim analysis, *post hoc* power analysis was then performed using a Mann–Whitney *U*-test (two groups) with one-sided α level of 0.05. If the power did not reach a value ≥ 0.8, an estimated sample size which should be achieved further in the study was calculated to find the intervention effect at a power of 0.8 ($\alpha = 0.05$). For sample size and statistical power calculations, we used the analysis software G*Power (version 3.1.9.2, Heinrich-Heine-University, Duesseldorf, Germany).

Results

Thirty-four patients (10 women and 24 men) were included in the study. Of these, 19 were randomized to the intervention group and 15 to the control group, Fig. 2). Enrolment in the study was terminated because the first interim analysis showed the study was sufficiently powered to detect significant differences among 34 patients, with effect sizes >0.8. For example, the smallest effect size (d = 1.036) in this case achieved a power of 0.88 with a one-sided alpha level of 0.05. Demographics, baseline characteristics, medical history and type of anesthesia are presented in Table 1.

No statistically significant differences were found in age, gender, localization of stroke, vascular territory or distribution of anesthesia between the groups. In general, there was a significant increase in most dysphagia severity scores for the patients in the intervention group immediately after TEE. The results for both groups are summarized in Tables 1 and 2.

Table 1 Demographics, baseline characteristics, medical history ($N = 34$)

Demographics		$n = 15$ (control group)	$n = 19$ (intervention group)	P
Age, mean (SD), years	71 (11.30)	73 (10.23)	70 (12.15)	0.396
Sex, *n* (%)				
Women	10 (29.4)	5 (33.3)	5 (26.3)	0.718
Men	24 (70.6)	10 (66.7)	14 (73.7)	
Baseline characteristics				
Admission NIHSS score, mean (SD)	4.68 (4.25)	5.67 (4.64)	3.89 (3.87)	0.264
Discharge NIHSS score, mean (SD)	3.00 (3.38)	3.93 (4.16)	2.32 (2.58)	0.221
Admission NIHSS Δ discharge NIHSS, *P*		0.005*	0.032*	
Admission mRS score, mean (SD)	2.73 (1.56)	3.13 (1.41)	2.42 (1.64)	0.174
Discharge mRS score, mean (SD)	2.05 (1.56)	2.53 (1.73)	1.68 (1.34)	0.138
Admission mRS Δ discharge mRS, *P*		0.088	0.013*	
Admission BI score, mean (SD)	57.8 (37.28)	47.33 (36.75)	66.05 (36.54)	0.099
Discharge BI score, mean (SD)	73.2 (35.27)	59.00 (38,74)	84.47 (28.47)	0.012*
Admission BI Δ discharge BI, *P*		0.018*	0.002*	
Medical history				
Localization of stroke, *n* (%)				
Left hemisphere	19 (55.9)	5 (33.3)	14 (73.7)	0.055
Right hemisphere	13 (38.2)	9 (60)	4 (21.1)	
Both hemispheres	2 (5.9)	1 (6.7)	1 (5.3)	
Vascular territory, *n* (%)				
Anterior	3 (8.8)	3 (20)	0	0.065
Media	20 (58.8)	10 (66.7)	10 (52.6)	
Posterior	5 (14.7)	0	5 (26.3)	
Vertebrobasilar	5 (14.7)	2 (13.3)	3 (15.8)	
Several	1 (2.9)	0	1 (5.3)	
Distribution of anesthesia during TEE, *n*(%)[a]	$n = 32$	$n = 15$	$n = 17$	0.723
Propofol i.v.	16 (50)	8 (53.3)	8 (47.1)	
Propofol i.v. and local anesthesia of the pharynx	16 (50)	7 (46.7)	9 (52.9)	

△, within-group effect between admission and discharge; BI, Barthel index; i.v., intravenous; mRS, modified Rankin Scale; *n*, number of cases; NIHSS, National Institutes Health Stroke Scale; *P*, *P*-value for between group comparison; TEE, transesophageal echocardiography. [a]Two participants refused the application of anesthesia during TEE. *Significant.

Secretion Severity Rating Scale and Penetration-Aspiration Scale for saliva

Compared to the control group, the intervention group showed an increase in SSRS and PAS immediately after TEE (Table 2).

Penetration-Aspiration Scale for liquid boli

A between-group comparison revealed a significant increase in PAS score for the intervention group immediately after TEE for small and large liquid boli. The effect lasted 24 h after TEE for large liquid boli (Table 2).

Yale Pharyngeal Residue Severity Scale score for valleculae

Compared to the control group, the intervention group showed an increase in the YS score for residue severity in valleculae immediately after TEE (for small and large liquid boli, pureed and solid boli) and 24 h after TEE (for small and large liquid boli, pureed and solid boli) (Table 2).

Yale Pharyngeal Residue Severity Scale score for piriform sinus

The YS score for residue severity in piriform sinus in the intervention group increased immediately after TEE (for small and large liquid boli; Table 2).

National Institutes of Health Stroke Scale, modified Rankin scale and Barthel index

The NIHSS, mRS and BI improved in both groups over time, with no significant difference between the groups. With the exception of mRS in the control group, scores for all three measures improved in both groups between admission and discharge. There were no statistically significant differences in the respective scores between the groups except for Barthel index score at discharge, which showed a statistically significant advantage for the intervention group (Table 1).

Table 2 Interaction-effect between time points and groups for Secretion Severity Rating Scale, Penetration-Aspiration Scale, Yale Pharyngeal Residue Severity Ratings Scale for valleculae and piriform sinus, and Functional Oral Intake Scale

	Before TEE (T1)				Immediately after TEE (T2)				24 h after TEE (T3)				Time-group interaction effect (T2ΔT1)			Time-group interaction effect (T3ΔT1)		
	Group				Group				Group									
	Control		Intervention		Control		Intervention		Control		Intervention							
	x̄ (s)	*n*	x̄ (s)	*n*	x̄ (s)	*n*	x̄ (s)	*n*	x̄ (s)	*n*	x̄ (s)	*n*	*P*	r	z	*P*	r	z
SSRS	2.00 (1.20)	15	0.63 (0.96)	19	1.73 (1.16)	15	1.95 (1.03)	19	1.33 (1.11)	15	1.32 (0.95)	19	<0.001**	0.75	−4.379	<0.001**	0.61	−3.551
PAS saliva	2.80 (2.31)	15	1.21 (0.63)	19	2.53 (2.39)	15	2.58 (1.71)	19	2.20 (2.46)	15	1.63 (1.17)	19	<0.001**	0.61	−3.532	0.007*	0.46	−2.704
PAS small liquid	3.69 (2.92)	13	1.68 (1.69)	19	3.54 (2.73)	13	2.42 (2.26)	19	2.77 (2.33)	13	1.63 (1.60)	19	0.009*	0.46	−2.601	0.059	0.33	−1.892
PAS large liquid	2.63 (2.29)	8	1.56 (1.32)	16	2.25 (2.28)	8	2.94 (2.44)	16	2.13 (2.32)	8	1.88 (1.73)	17	0.009*	0.53	−2.609	0.025*	0.45	−2.241
PAS puree	1.46 (0.84)	13	1.26 (0.64)	19	1.46 (0.84)	13	1.63 (1.63)	19	1.31 (0.72)	13	1.37 (0.74)	19	0.235	0.21	−1.189	0.156	0.25	−1.417
PAS solid	1.09 (0.29)	11	1.00 (0.00)	19	1.09 (0.29)	11	1.00 (0.00)	19	1.09 (0.29)	11	1.00 (0.00)	19	1.000	0.00	0.000	1.000	0.00	0.000
YS-V small liquid	2.15 (0.66)	13	1.68 (0.65)	19	1.77 (0.58)	13	2.05 (0.76)	19	1.70 (0.72)	13	1.95 (0.69)	19	0.003*	0.52	−2.931	0.022*	0.41	−2.293
YS-V large liquid	2.63 (0.70)	8	2.00 (0.61)	16	2.38 (0.70)	8	2.50 (1.00)	16	2.25 (0.66)	8	2.31 (0.68)	17	0.013*	0.51	−2.490	0.009*	0.52	−2.618
YS-V puree	2.92 (0.62)	13	2.37 (0.93)	19	2.54 (0.63)	13	2.79 (0.95)	19	2.46 (0.63)	13	2.53 (0.82)	19	0.001*	0.59	−3.354	0.010*	0.46	−2.587
YS-V solid	2.00 (1.04)	11	1.58 (0.99)	19	1.91 (1.08)	11	1.89 (1.29)	19	1.64 (0.98)	11	1.68 (0.98)	19	0.033*	0.39	−2.130	0.039*	0.38	−2.064
YS-PS small liquid	1.92 (0.47)	13	1.63 (0.58)	19	1.77 (0.58)	13	1.89 (0.64)	19	1.62 (0.62)	13	1.74 (0.55)	19	0.021*	0.41	−2.312	0.061	0.33	−1.870
YS-PS large liquid	2.38 (0.70)	8	2.00 (0.61)	16	2.13 (0.60)	8	2.19 (0.63)	16	2.00 (0.50)	8	2.06 (0.66)	17	0.038*	0.42	−2.076	0.077	0.35	−1.769
YS-PS puree	2.23 (0.70)	13	1.95 (0.76)	19	2.15 (0.66)	13	2.11 (0.72)	19	2.08 (0.73)	13	1.89 (0.55)	19	0.127	0.27	−1.524	0.593	0.09	−0.535
YS-PS solid	1.36 (0.88)	11	1.16 (0.36)	19	1.36 (0.88)	11	1.26 (0.55)	19	1.27 (0.62)	11	1.26 (0.55)	19	0.447	0.14	−0.761	0.149	0.26	−1.443
FOIS	5.07	15	6.63	19	5.27	15	5.84	19	5.40	15	6.05	19	<0.001**	0.59	−3.426	<0.001**	0.55	−3.201

Δ, interaction-effect between time points and groups; FOIS, Functional Oral Intake Scale; PAS, Penetration Aspiration Scale; r, effect size; SSRS, Secretion Severity Rating Scale; T, time-point; YS-PS, Yale Pharyngeal Residue Severity Rating Scale for piriform sinus; YS-V, Yale Pharyngeal Residue Severity Rating Scale for valleculae; z: z-standardized U-value. Decreasing FOIS scores indicate a deterioration in oral intake; increasing SSRS and PAS scores indicate higher aspiration risk and increased dysphagia severity; increasing YS scores indicate increased dysphagia severity. *Significant; **Highly significant.

Functional Oral Intake Scale

The FOIS showed a statistically significant decline in scores immediately after and 24 h after TEE for the intervention group, but not for the control group (Table 2).

With regard to the dichotomized PAS scores [aspiration: yes (PAS $\geq$ 6)/aspiration: no (PAS < 6)] no statistically significant between-group differences were found at the different test time points.

Discussion

The results of the TEDRAS trial in acute stroke patients showed a significant increase in all dysphagia outcome scores in the intervention group immediately after TEE in the between-group comparisons for saliva, and small and large liquid boli. A significant increase in the YS score was found in this group for all consistencies in the valleculae and for small and large liquid bolus in the piriform sinus. These results correspond to the results of the study by Grimm *et al.* [18], who found residue to be the most frequent dysphagia symptom in patients who had undergone intra-operative TEE as diagnosed via videofluoroscopy.

In acute stroke management TEE is established as a routine examination to identify possible sources of cardiac embolism in the etiology of stroke [28]. However, transient hoarseness and sore throat were reported after routine TEE [29], as well as swallowing difficulties after intra-operative TEE during cardiac surgery, with a 4% incidence of dysphagia and 90% occurrence of aspiration in these patients [15].

Normal swallowing consists of two main components [30]: movement forces that propel, clear and direct the bolus into the esophagus, and valving forces (velopharyngeal and laryngeal valving) that protect the airway from penetration and aspiration. Impairment in the movement of any of the relevant anatomic structures, in their motor control or sensation may lead to impaired swallowing. Relevant movements for propulsion, clearance and direction of bolus include tongue posterior thrust, pharyngeal squeeze and laryngeal elevation; valving forces are supported by laryngeal elevation.

The perceived symptoms of the increase in severity scores for saliva management, penetration, aspiration and pharyngeal residue of liquids and food immediately after TEE in the intervention group may have several causes: mechanical irritation of the sensitive pharyngolaryngeal mucosa by the TEE probe may cause stronger salivation, but may also damage peripheral sensation and negatively impact tongue posterior thrust, pharyngeal squeeze and laryngeal elevation. The mechanical influence of the TEE probe on anatomic structures relevant for swallowing needs to be considered in relation to the size and volume of the oral cavity and tongue. The TEE probe has a 10.5-mm diameter and weighs 1.5 kg [31]. It is reported that the average maximum mouth opening in humans is 52.02 $\pm$ 5.09 mm [32]. The average volume of the tongue is 47 070 $\pm$ 7080 mm^3 and the maximum capacity of the oral cavity is 51 470 $\pm$ 6460 mm^3 [33]. Considering the diameter and weight of the TEE probe and the anatomical proportions of the human oral cavity and tongue, we hypothesize that the TEE probe applies a too high pressure to oral, pharyngeal and laryngeal tissues, causing damaged motility of tongue and tongue base, pharyngeal wall, larynx and eventually of the upper esophageal sphincter.

The TEDRAS trial has some limitations, including the design and sample sizes, which did not allow statistical evaluation of clinical complications such as aspiration pneumonia after TEE. The study findings should be interpreted with caution since we relied on only one assessor for dysphagia ratings. Furthermore, the small sample size may have led to bias due to different baseline characteristics such as small difference in mean NIHSS between groups and significantly more right hemispheric infarctions. The prospective randomized trial by Chin *et al.* [17] confirmed the negative influence of long duration of intra-operative TEE placement in the oesophagus on swallowing in cardiac patients, while, in the present cohort, the impact of the duration of TEE on swallowing was not examined.

With significant results with regard to SSRS, PAS and YS scores for saliva and liquid boli as well as YS for valleculae score for all consistencies, the results of the TEDRAS trial give the first cautious indication of a negative influence of TEE on swallowing in patients with acute stroke, even those who present with mild or no dysphagia after stroke and before TEE. We recommend including special caution after TEE in acute stroke patients with either a strict indication for obligatory FEES after TEE or a strict fasting period of 24 h after TEE. With regard to FEES after TEE, diet restriction is not indicated for patients with PAS scores <4. The results of the TEDRAS trial suggest that the development of a diagnostic algorithm is required for FEES in patients with acute stroke undergoing TEE.

Acknowledgement

The authors thank all patients for participating in the TEDRAS trial.

Funding information: No funding was received for this trial. Open access funding enabled and organized by Projekt DEAL.

Disclosure of conflicts of interest

M.B. reports grants from the German Heart Research Foundation and the William G. Kerckhoff Foundation, outside the submitted work. S.H., T.B., H.K., S.W., M.Y., T.G., P.S. and M.J. have nothing to disclose.

Data availability statement

The data that support the study's findings are not publicly available due to privacy and ethical restrictions set by the Research Ethic Committee of the Faculty of Medicine at the Justus-Liebig-University. All data are stored at the Department of Neurology of the Justus-Liebig-University as re-identifiable information in a password-protected computer database. The database summarizes the evaluated group findings. No personal information of the participating patients is identifiable. Access to the data is restricted to the listed investigators. Upon request, we can supply aggregate group data. In this case, you may contact the corresponding author, Ms. Samra Hamzic.

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