**ABSTRACT**

**Objective:** To assess safety and feasibility of real-time (RT) MRI for evaluation of dysphagia and to compare this technique to standard assessment by flexible endoscopic evaluation of swallowing (FEES) and videofluoroscopy (VF) in a cohort of patients with inclusion body myositis (IBM).

**Methods:** Using RT-MRI, FEES, and VF, an unselected cohort of 20 patients with IBM was studied as index disease with a uniform dysphagia. Symptoms of IBM and dysphagia were explored by standardized tools including Swallowing-Related Quality of Life Questionnaire (SWAL-QoL), IBM Functional Rating Scale, Patient-Reported Functional Assessment, and Medical Research Council Scale.

**Results:** Dysphagia was noted in 80% of the patients and SWAL-QoL was impaired in patients with IBM compared to published reference values of healthy elderly. Swallowing in a supine position during RT-MRI was well-tolerated by all patients. RT-MRI equally revealed dysphagia compared to VF and FEES and correlated well with the SWAL-QoL. Only RT-MRI allowed precise time measurements and identification of the respective tissue morphology. The pharyngeal transit times were 2-fold longer compared to published reference values and significantly correlated with morphologic abnormalities.

**Conclusions:** RT-MRI is safe and equally capable as VF to identify the cause of dysphagia in IBM. Advantages of RT-MRI include visualization of soft tissue, more reliable timing analysis, and lack of X-ray exposure. RT-MRI may become a routine diagnostic tool for detailed assessment of the esophagus and other moving parts of the body, facilitating longitudinal evaluations in daily practice and clinical trials. *Neurology® 2016;87:1–7*

**GLOSSARY**

CI = confidence interval; CP = cricopharyngeal propulsion; EOT = esophageal opening time; FEES = flexible endoscopic evaluations of swallowing; IBM = inclusion body myositis; IBM-FRS = IBM Functional Rating Scale; MRC = Medical Research Council; OTT = oral transfer time; PTT = pharyngeal transfer time; ROI = region of interest; RT-MRI = real-time MRI; SWAL-QoL = Swallowing-Related Quality of Life; UES = upper esophageal sphincter; VF = videofluoroscopy.

Dysphagia is common in neurodegenerative disorders (e.g., Parkinson disease), myopathies, and stroke, and is associated with a reduced quality of life and life-threatening complications (e.g., aspiration pneumonia). Yet diagnostic tools for evaluating dysphagia are not fully developed and despite significant radiation exposure, videofluoroscopy (VF) has remained the gold standard in swallowing diagnostics for almost 2 decades. The addition of flexible endoscopic evaluations of swallowing (FEES) could not replace VF. Both are used for descriptive analyses and the Rosenbek penetration-aspiration scale is mainly used to classify the degree of dysphagia. Quantitative measures have methodical restrictions of FEES and VF. A reliable method that can be repeated without X-ray exposure and the possibility to visualize the soft tissue is highly desirable in daily routine as well as for clinical studies.

Preceding studies of healthy individuals demonstrated that a novel method of real-time MRI (RT-MRI) was suitable to display the course of swallowing. In the present study, assessed...
the safety and feasibility of this novel RT-MRI as a diagnostic tool in patients with dysphagia. RT-MRI was compared to VF and FEES with regard to morphologic and functional findings.

As index disease with dysphagia, we studied an unselected cohort of patients with inclusion body myositis (IBM) as they often have dysphagia.8–11

METHODS Participants. Twenty consecutive patients were recruited from the local Department of Neurology between 2012 and 2014. Diagnosis of IBM was based upon the most recent European Neuromuscular Centre criteria.12 Absence of severe aspiration was confirmed by medical history and FEES examination per Langmore criteria.9 Data collection was scheduled for one visit.

Standard protocol approvals, registrations, and patient consents. The study was in accord with good clinical practice and approved by the local ethics committee and all participants gave written informed consent prior to examination.

Questionnaires and clinical examination. To assess the influence of dysphagia on quality of life, we used the Swallowing-Related Quality of Life (SWAL-QoL) questionnaire. This patient-based questionnaire ranges from 100 points (normal swallowing) to 0 points (major dysphagia). The SWAL-QoL is validated13 and was used for assessing dysphagia in amyotrophic lateral sclerosis and Parkinson disease.14,15 The IBM Functional Rating Scale (IBM-FRS) and the Patient-Reported Functional Assessment for patients with IBM were used to assess function. Muscle strength was evaluated by Medical Research Council (MRC) scale (0 to 5) and with IBM were used to assess control of the bolus, (2) bolus transport, (3) velo-pharyngeal closure, (4) retractions of the bolus in the pharyngeal tract, (5) laryngeal penetration, and (6) aspiration, which were all arbitrarily graded on a 4-point-scale (3 = normal, 0 = severe pathology). Evaluations of all methods were performed by 2 independent specialists, who were masked for each other’s score and all results of other methods. The mean of both scorings was used for subsequent analysis.

Image analysis. Clinical function and morphology. VF, FEES, and RT-MRI results were evaluated according to (1) the oral control of the bolus, (2) bolus transport, (3) velo-pharyngeal closure, (4) retractions of the bolus in the pharyngeal tract, (5) laryngeal penetration, and (6) aspiration, which were all arbitrarily graded on a 4-point-scale (3 = normal, 0 = severe pathology). Evaluations of all methods were performed by 2 independent specialists, who were masked for each other’s score and all results of other methods. The mean of both scorings was used for subsequent analysis.

Quantitation of swallowing events. For quantitative evaluation, the viewing software OsirIX MD (open-source software: osirix-viewer.com) was used. Start and end points of distinct deglutition events were analyzed frame by frame in the most relevant sagittal view.9,10 For relative timings, the oro-velar opening (velum elevation from dorsum of tongue) was chosen as start time.7 Measures focused on oral transfer time (OTT; from start to oro-velar closure), pharyngeal transfer time (PTT; bolus passage from pharynx to esophagus), and esophageal opening time (EOT; from opening until closure of the upper esophageal sphincter [UES]). Laryngeal elevation and the extent of the morphologic finding of the UES were measured in millimeters per region of interest (ROI) tool from OsirIX MD. All timings were assessed in consensus by 2 masked specialists.

Statistical analyses. Bland-Altman plots (including 95% limits of agreement) were used to investigate the agreement among the 3 techniques, i.e., FEES, VF, and RT-MRI.19 The interrater agreement was assessed by the Krippendorff α coefficient.20 Associations between variables were assessed by Pearson correlation coefficients. Comparison between 2 groups was made by t test. Statistical analyses were performed using the software GraphPad Prism 6 (San Diego, CA) and SAS version 9.4 (Cary, NC). Due to the exploratory nature of this investigation, p values were not adjusted for multiple testing and p values ≤ 0.05 were considered significant.

RESULTS Characterization of the patient cohort. Twenty-two unselected patients with IBM were included in this study and 2 patients were subsequently excluded: one could not be lifted onto the MRI table; another patient died from a ruptured aortic aneurysm before the planned assessments. The results of all 20 participants were used for analysis (overview of all raw data in table e-1). Twelve participants were men (60%); the mean age (±SD) was 72 ± 7 years.
SWAL-QoL revealed a broad range of the severity of dysphagia within the patient cohort and the scores were pathologic compared to previously validated values in aged individuals without dysphagia.\textsuperscript{15,21} Eighty percent of the patients displayed symptoms of dysphagia. A correlation between restrictions in daily life activities (IBM-FRS), muscle strength (MRC scale), and the patient-reported measure of swallowing (SWAL-QoL) were observed (figure e-1: MRC vs IBM-FRS: $r = 0.83$, 95% confidence interval [CI] 0.61–0.93, $p = 0.0001$; SWAL-QoL vs IBM-FRS: $r = 0.6$, 95% CI 0.22–0.82, $p = 0.0051$). No statistically significant correlation was noted between positivity for the Mup44 autoantibody (9 out of 20 patients were positive, table e-1) and any patient-reported outcome scale or results of the technical assessments (not shown).

Assessment of swallowing by FEES, VF, and RT-MRI. A cricopharyngeal propulsion (CP) in the region of the UES was identified during swallowing by VF and RT-MRI, but not by FEES (figure 1). In VF, the CP appeared similar to a cricopharyngeal bar that can be observed, e.g., in the Zenker diverticulum, which was not observed in our cohort. At rest, T2-weighted MRI revealed no morphologic abnormalities or CP within the esophagus, which excluded other causes for dysphagia, such as a tumor.

Relevant parameters of swallowing included bolus control and transport, velo-pharyngeal closure, laryngeal penetration, aspiration, and bolus retention in the pharyngeal tract. The latter is believed to be the most sensitive indicator of functional deficits in swallowing and was reliably identified by all 3 modalities (FEES, VF, RT-MRI). This parameter was scored by 2 independent investigators using a 4-point scale (figure 2A). Bland-Altman plots did not reveal any systematic deviation between these methods (figure 2B). Penetration was seen in 2 patients (10%) by RT-MRI and in 6 patients (30%) by FEES or VF. Aspiration was suspected by one rater in one patient by FEES and RT-MRI and in 3 patients by VF. The interrater agreement was assessed for bolus transport and retention. The Krippendorff $\alpha$ was 0.39 (RT-MRI), 0.55 (VF), and 0.67 (FEES) for bolus transport, and 0.51 (RT-MRI), 0.52 (VF), and 0.52 (FEES) for retention. Penetration and aspiration were rare events and the scoring was mostly 3 on the aforementioned 4-point scale, rarely 2, and never 1 or 0. Since standard measures for interrater agreement including the Krippendorff $\alpha$ are corrected for random agreement, under these conditions, a statistical paradox occurs\textsuperscript{22} with the measure for agreement suggesting a low degree of agreement although the observed agreement is very high. Therefore, no formal assessment of interrater agreement is reported here for penetration and aspiration.

Aspiration was clinically unapparent and episodes were not accompanied by symptoms like coughing or dyspnea. All patients felt comfortable with swallowing in a supine position and even preferred this compared to sitting during VF. The self-assessment of patients by SWAL-QoL correlated to the grade of retention as reflected by RT-MRI, VF, and FEES (RT-MRI vs SWAL-QoL: $r = 0.52$, 95% CI 0.11–0.79,
Technical impairments prevented a reliable analysis of 1 VF and 1 FEES so that these data had to be excluded. Quantitative analysis of bolus transport, laryngeal elevation, and CP by RT-MRI. The OTT was 411 ± 200 milliseconds (all data mean ± SD), the PTT was 1,579 ± 1,561 milliseconds, and the EOT was 324 ± 65 milliseconds. Measurements for OTT and EOT were prolonged compared to normal reference values, which have been recently established using the same MRI technique7 (OTT: difference between means = 215 ± 66, 95% CI 80–350, p = 0.0030; EOT; difference between means = 72 ± 23, 95% CI 25–119, p = 0.0041; figure e-2A). The values for PTT were much higher, including one extremely high value (PTT: difference between means = 999 ± 499, 95% CI −22 to 2,021, p = 0.0547 vs normal reference values; figure e-2A). A CP was noted in 15 patients and its extent was 5.54 ± 3.39 mm (mean ± SD). Due to technical limitations, CP could not be analyzed in 2 RT-MRI. The extent of CP correlated with the PTT (r = 0.67, 95% CI 0.28 to 0.87, p = 0.0031; figure e-2B). An impaired laryngeal elevation is thought to play a role during dysphagia in IBM.11 The mean laryngeal elevation as determined by RT-MRI was 30.8 ± 9.01 mm (mean ± SD), yet this did not significantly correlate to the severity of dysphagia assessed per SWAL-QoL, the extent of the CP, or the transportation times (data not shown). The laryngeal elevation was also analyzed in VF and compared to RT-MRI. The analysis of VF was technically limited, partly due to radiation safety constraints with slow frame rates. The analysis relied on measurement of the laryngeal elevation in relation to the third cervical vertebra (C3), which was possible in 14 of 20 VF and in all RT-MRI. In relation to C3, we observed a mean laryngeal elevation (±SD) of 1.91 ± 0.6 in RT-MRI and 1.62 ± 0.57 in VF. This finding was in range of previously published data of normal laryngeal elevation in VF23,24 and there was no significant correlation to SWAL-QoL (data not shown). The Bland-Altman method comparison revealed a systematic deviation with higher values in RT-MRI (data not shown). Collectively, these data suggest that CP but not laryngeal elevation is a crucial component of dysphagia in IBM.

**DISCUSSION** Swallowing is an essential function of the body and the impairment of swallowing—dysphagia—is a common symptom in various neurologic disorders. VF, the present standard for assessment of dysphagia, is limited in 3 ways: (1) a considerable amount of X-ray exposure is required; (2) demonstration of soft
tissue is restricted; and (3) aberration of images impair absolute measurements. Dynamic CT images with a time resolution of 10 fps carry the disadvantages of X-ray exposure and a restricted time resolution.

IBM serves as an ideal group of patients for a clinical application of RT-MRI as a diagnostic tool for the evaluation of swallowing since (1) patients with IBM have a typical type of dysphagia; (2) not all patients have dysphagia, which enables an ideal comparison within this cohort; (3) the disease does not impair cognition or memory, so that informed consent and cooperation are unaffected. In line with our previous study, RT-MRI in a supine position was well-tolerated by all participants. The frequency of 80% of dysphagia was well in line with previous observations. Despite a major relevance of dysphagia in IBM including associations with cachexia, pneumonia, and increased mortality, dysphagia is often overlooked and may be more readily picked up by the routine use of standardized questionnaires.

For the evaluation of swallowing, an arbitrary, self-designed 4-point scale was used instead of the established Rosenbek penetration-aspiration scale. This was necessary because patients with aspiration were excluded and retention is not assessable with the Rosenbek scale. Retention is seen as the most sensitive marker for dysphagia even in clinically unapparent cases. Penetration is a potential risk factor for aspiration and represents a clinical rise to severe dysphagia. The lower rate of detection of penetration by RT-MRI (10% in RT-MRI vs 30% in FEES and VF) may be due to a smaller bolus of only 5 mL in RT-MRI. In addition, due to logistical issues, the assessments could not always be performed on the same day. Third, validity of the data is impaired by the small size of the cohort. A future evaluation of a larger cohort will include the use of a 10-milliliter bolus, which, for safety reasons, was avoided in this initial study.

In contrast to VF, RT-MRI provided quantitative functional and morphologic pathologies. In VF, dimensional measurements suffered from aberration of image scales and software embedment. Due to a 1:1 image scale in RT-MRI, measures of laryngeal elevation and morphologic dimension were easily accomplished using digital ROI tools from a standard digital imaging and communications in medicine viewer. Combined with the superior illustration of soft tissues, the novel RT-MRI method was favored for structural and functional measures of morphologic structures. Functional measures referred to timings of oral, pharyngeal, and esophageal bolus transport and to the extent of laryngeal elevation and the size of the CP. Our data comparison with reference values from a former study with healthy young volunteers suffers from a significant difference of age. The preliminary result of prolonged transport timings in IBM has to be proved in groups of age-adapted samples.

Other groups have assessed the pressure profile of the oropharynx and hypopharynx and the manometry...
of the UES. However, these data are inconsistent and failed to provide a reliable profile in IBM.11,29 Therefore, our present study was focused on the comparison of imaging techniques. Future studies will aim to identify the clinicomorphologic dysfunction that causes dysphagia in IBM, possibly a weakness of suprahyaloidal muscles, which disturbs the precise concert of contraction of swallowing muscles and impairs the bolus transport across the UES.

Because of technical restrictions in clinical routine examination, neither VF nor FEES exceeded the evidence level of qualitative analyses and descriptive reports. Recently, ultrasonographic B-mode videos were compared to VF and FEES in order to detect dysphagia but did not reach equivalent sensitivity.30 By contrast, RT-MRI provides the basis for a quantitative assessment of functional as well as structural findings during swallowing. The advantage of quantitative data in dysphagia will be, e.g., a longitudinal evaluation of therapeutic interventions.

Using VF, other groups reported a number of different assumptions about the UES morphology and its presumed impairment of contraction in IBM. An impaired laryngeal elevation and a failed relaxation of the UES were discussed as underlying mechanisms for dysphagia in IBM.8,10,11,29,31 Our present study confirms that CP is a major morphologic abnormality in IBM and could also be interpreted as functional achalasia of the UES. Accordingly, a significant correlation to the duration of the PTT was demonstrated. However, our present RT-MRI and VF analysis of laryngeal elevation did not reveal any major abnormalities. Moreover, there was no significant correlation between laryngeal elevation and the degree of dysphagia or the extent of the CP. In contrast to previous observations by others, an impaired laryngeal elevation was not observed in our study. This may be explained by the nature of our IBM cohort and exclusion of patients with severe dysphagia and history of aspiration. We noted a systematic deviation with higher values for the laryngeal elevation in RT-MRI compared to VF in Bland-Altman analysis. Bearing in mind the possible bias of a small cohort (n = 14) that encompassed quantifiable data of laryngeal elevation per 2 different methods (RT-MRI and VF), this finding might suggest that different forces of gravity in different body positions could affect swallowing to some degree.

RT-MRI was demonstrated to be noninferior compared to the standard assessments VF and FEES. Assessment in a supine position did not cause disadvantages or unwanted events. It is expected that RT-MRI will develop as a useful diagnostic tool for assessment of dysphagia in various conditions. Further studies with RT-MRI are planned to determine the causes and degrees of dysphagia in other myopathies and other neurologic and non-neurologic disorders that impair swallowing.

**AUTHOR CONTRIBUTIONS**
Arno Olthoff designed the study, supervised the study, acquired and analyzed the data, interpreted the data, drafted the manuscript, and revised the manuscript. Per-Ole Carstens acquired and analyzed the data, interpreted the data, drafted the manuscript, and revised the manuscript. Shao Zhang acquired and analyzed the data. Eva von Fintel acquired and analyzed the data. Tim Friede revised the manuscript and conceived and assisted with the statistical analyses. Joachim Lotz supervised the study, interpreted the data, and revised the manuscript. Jens Frahm designed and supervised the study. Jens Schmidt designed and supervised the study, interpreted the data, and revised the manuscript.

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**DISCLOSURE**
A. Olthoff reports no disclosures relevant to the manuscript. P.-O. Carstens has received reimbursements for travel from Allergan, CSL Behring, Grifols, and Vital Aire. S. Zhang and E. von Fintel report no disclosures relevant to the manuscript. T. Friede served in the past 3 years or serves currently as a consultant (including data monitoring committees and advisory boards) to Novartis, Biogen, Grünenthal, AstraZeneca, Bayer, Jansen, SGS, and Pharmacol. J. Lotz and J. Frahm report no disclosures relevant to the manuscript. J. Schmidt received honoraria, research grants, or reimbursements for travel from Bayer, Biogen, BioMarin, Biocrest, CSL Behring, Grifols, Novartis, Ocatpharma, and Vital Aire. Go to Neurology.org for full disclosures.

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Table e-1: Overview of all data

Demographics, treatment, clinical and technical data of all patients. Clin.-pathol.: clinico-pathologically defined IBM; clinical: clinically defined IBM; prob.: probable IBM; Mup44: Autoantibody directed to cytosolic 5’-nucleotidase 1A (cN1A); MRC: Medical Research Council; IBM-FRS: IBM functional rating scale; sIFA: patient reported functional assessment for patients with IBM; SWAL-QoL: swallowing quality of life scale; RT-MRI: real-time magnetic resonance imaging; VF: videofluoroscopy; FEES: flexible endoscopic evaluation of swallowing; OTT: oral transit time; EOT: esophageal opening time; PTT: pharyngeal transit time; CP: cricopharyngeal propulsion; n.v.: no value (due to technical impairments, one VF and one FEES had to be excluded and laryngeal elevation could not be analyzed in one RT-MRI and CP could not be analyzed in two RT-MRI).

Figure e-1: Correlation of functional IBM scale and MRC score with swallowing scale.

A statistically significant correlation was noted between the impairment of daily life activity per IBM-FRS and the muscle strength per clinical examination (MRC sum-score) (A) as well as between an impaired swallowing per swallowing quality of life scale (SWAL-QoL) and IBM-FRS (B). (normal values: IBM-FRS= 40, MRC= 140, SWAL-QoL= 100; sIFA= 0; degree of retention per RT-MRI/VF/FEES= 3; 0= most severe impairment in all scales except for the sIFA [max. severity= 110]).

Figure e-2: Quantitative assessment of RT-MRI

A) Quantitative analysis of real-time MRI of swallowing in IBM patients shows a significantly prolonged oral transit time and esophageal opening time compared to healthy non-dysphagic controls (*reference values from 6). The values for the pharyngeal transit time are borderline. Statistical analysis was performed by t-test as detailed in the Methods section. B) Significant correlation between the extent of the cricopharyngeal propulsion and the pharyngeal transit time. Exclusion of two data sets was required due to technical impairment of one VF and one FEES. OTT: oral transit time; PTT: pharyngeal transit time; EOT: esophageal opening time.
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<th>Treatment</th>
<th>MRC</th>
<th>IBM-FRS</th>
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Figure e-1

A

MRC (sum score) vs IBM-FRS (sum score)

$r=0.83$

$p<0.0001$

B

SWAL-QoL (%) vs IBM-FRS (sum score)

$r=0.60$

$p=0.0051$
Figure e-2

A

Time (ms)

p<0.0001  p=0.0547  p=0.0041

Control#
IBM

OTT  PTT  EOT

B

PTT (ms)

r=0.67  p=0.0031

Cricopharyngeal propulsion (mm)
Videos 1 to 6:
The movies show exemplary findings of swallowing in patients with IBM: Normal swallowing (Video 1) and dysphagia (Video 2) in RT-MRI; Normal swallowing (Video 3) and dysphagia (Video 4) in VF; Normal swallowing (Video 5) and dysphagia (Video 6) in FEES.

Video 1: Normal swallowing – RT-MRI
Video 2: Relevant dysphagia – RT-MRI
Video 3: Normal swallowing – VF
Video 4: Relevant dysphagia – VF
Video 5: Normal swallowing – FEES
Video 6: Relevant dysphagia – FEES