

## Effect of Dysphagia Screening Strategies on Clinical Outcomes After Stroke

### A Systematic Review for the 2018 Guidelines for the Early Management of Patients With Acute Ischemic Stroke

*Reviewed for evidence-based integrity and endorsed by the American Association of Neurological Surgeons and Congress of Neurological Surgeons*

*Endorsed by the Society for Academic Emergency Medicine and Neurocritical Care Society*

*The American Academy of Neurology affirms the value of this guideline as an educational tool for neurologists.*

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**Introduction**—Dysphagia screening protocols have been recommended to identify patients at risk for aspiration. The American Heart Association convened an evidence review committee to systematically review evidence for the effectiveness of dysphagia screening protocols to reduce the risk of pneumonia, death, or dependency after stroke.

**Methods**—The Medline, Embase, and Cochrane databases were searched on November 1, 2016, to identify randomized controlled trials (RCTs) comparing dysphagia screening protocols or quality interventions with increased dysphagia screening rates and reporting outcomes of pneumonia, death, or dependency.

**Results**—Three RCTs were identified. One RCT found that a combined nursing quality improvement intervention targeting fever and glucose management and dysphagia screening reduced death and dependency but without reducing the pneumonia rate. Another RCT failed to find evidence that pneumonia rates were reduced by adding the cough reflex to routine dysphagia screening. A smaller RCT randomly assigned 2 hospital wards to a stroke care pathway including dysphagia screening or regular care and found that patients on the stroke care pathway were less likely to require intubation and mechanical ventilation; however, the study was small and at risk for bias.

**Conclusions**—There were insufficient RCT data to determine the effect of dysphagia screening protocols on reducing the rates of pneumonia, death, or dependency after stroke. Additional trials are needed to compare the validity, feasibility, and clinical effectiveness of different screening methods for dysphagia. (*Stroke*. 2018;49:e123-e128. DOI: 10.1161/STR.000000000000159.)

**Key Words:** AHA Scientific Statements ■ deglutition disorders ■ stroke

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Dysphagia is a common consequence of stroke and a risk factor for aspiration pneumonia,<sup>1</sup> which is associated with higher rates of death and disability.<sup>2</sup> Methods for the assessment of aspiration risk include videofluoroscopy, fiberoptic endoscopic evaluation, and comprehensive speech pathology evaluation. However, these assessments require access to technology or specialty expertise with limited availability. Consequently, many hospitals use dysphagia screening protocols to identify patients who are at low risk of aspiration and who can then be safely given food, liquids, and medications.

Dysphagia screening protocols have been recommended for stroke patients.<sup>3</sup> However, only a limited number of screening protocols have been validated against gold standard assessments of aspiration risk.<sup>4,5</sup> There is considerable variation in dysphagia screening protocols across sites, and guidelines and performance measures for screening do not specify which protocols are best.<sup>6,7</sup> Furthermore, it is uncertain whether different swallowing assessments reduce the risk of pneumonia, disability, or death after stroke.

The writing committee for the “2018 Guidelines for the Early Management of Patients With Acute Ischemic Stroke”<sup>8</sup> commissioned an independent evidence review committee (ERC) to review evidence from randomized controlled trials (RCTs) for the effectiveness of dysphagia screening protocols for the prevention of aspiration pneumonia, disability, and death after stroke. The ERC addressed this question: In confirmed stroke patients, does dysphagia screening (or a quality improvement intervention including dysphagia screening), compared with no screening or usual care, decrease outcomes of pneumonia, death, or the combined end point of death or dependency? The ERC considered RCTs of different screening protocols, RCTs of interventions that included dysphagia screening as 1 element of a multidomain stroke unit intervention, and RCTs of quality improvement interventions designed to increase adherence to local dysphagia screening protocols.

## Methods

The ERC systematically reviewed randomized RCTs of dysphagia screening protocols or quality improvement interventions to standardize or increase dysphagia screening rates. Review methods adhered to the Preferred Reporting Items for Systematic Reviews and Meta-Analyses standards<sup>9</sup> with the recommendations of the “ACCF/AHA Clinical Practice Guideline Methodology Summit Report.”<sup>10</sup> Studies were considered eligible if they reported a randomized comparison of  $\geq 2$  dysphagia screening strategies, including quality improvement interventions designed to improve dysphagia screening rates or methods, and reported outcomes of death, disability, or pneumonia. Full inclusion and exclusion criteria are given in Table 1.

## Search Strategy

Medline (via PubMed/OVID), Embase (via OVID), and Cochrane Central Database of Controlled Trials (via CENTRAL) were searched on November 1, 2016, with the use of free text, medical subject headings, and synonyms for dysphagia screening in stroke patients. The fully specified search strategy is provided in Table I of the [online Data Supplement](#). Systematic reviews

or meta-analyses of studies meeting the selection criteria were checked by hand, and individual studies were included for extraction if they met the selection criteria. References of individual studies were also back-checked for relevant studies. The search strategy was developed by the ERC in consultation with Doctor Evidence (Santa Monica, CA) and carried out by Doctor Evidence medical librarians.

## Review for Eligibility

Doctor Evidence imported the search results into the DOC Library (Santa Monica, CA), a fully indexed central repository. Screening was performed against the predefined selection criteria (Table 1) developed by the ERC with the Doctor Evidence: Library Management System (Santa Monica, CA). The Library Management System is a web-based software platform featuring key word emphasis (coloring or bolding of key words), search and ranking functionalities, and the ability to assign and manage reasons for rejecting references at all stages of screening.

Title and abstract eligibility was performed by a Doctor Evidence medical librarian, with subsequent quality control performed by an independent reviewer. Additional quality control was performed by an independent Doctor Evidence methodologist validating all included abstracts and a random sample of excluded abstracts.

Full-text eligibility was performed by dual independent review by members of the ERC. Disagreements were resolved by the ERC chair.

## Quality Assessment

Two content ERC members independently assessed the risk of bias and applicability of each study using the Cochrane Risk for Bias tool,<sup>12</sup> version 5.1. Discrepancies were resolved by a third reviewer (the ERC chair). Study quality was not a criterion for eligibility for inclusion in the review.

## Data Abstraction

Data points and metadata were extracted from the articles by Doctor Evidence analysts and entered manually into the DOC Data 2.0 software platform (Santa Monica, CA) using a universal electronic extraction form and guided by a data configuration protocol with automated quality control features to prevent incorrect data-type entry. Each collected data point was verified manually against the source article by an independent reviewer (ie, single extraction with sequential quality control). Ontology management was undertaken to ensure consistency in naming characteristics and outcomes across all studies in a data set.

There were too few studies to perform a meta-analysis.

## Results

The review returned 448 articles, of which 20 were screened by full-text review to identify 3 relevant articles (Figure). Study quality is shown in Table 2. An overview of the study designs and main findings is shown in Table 3. Full details are provided in Table II in the [online Data Supplement](#).

The QASC study (Quality in Acute Stroke Care) was an RCT of a multidomain stroke unit intervention addressing fever, glucose control, and dysphagia management.<sup>13</sup> In this cluster randomized trial, 19 stroke units (1126 patients) were

**Table 1. Selection Criteria**

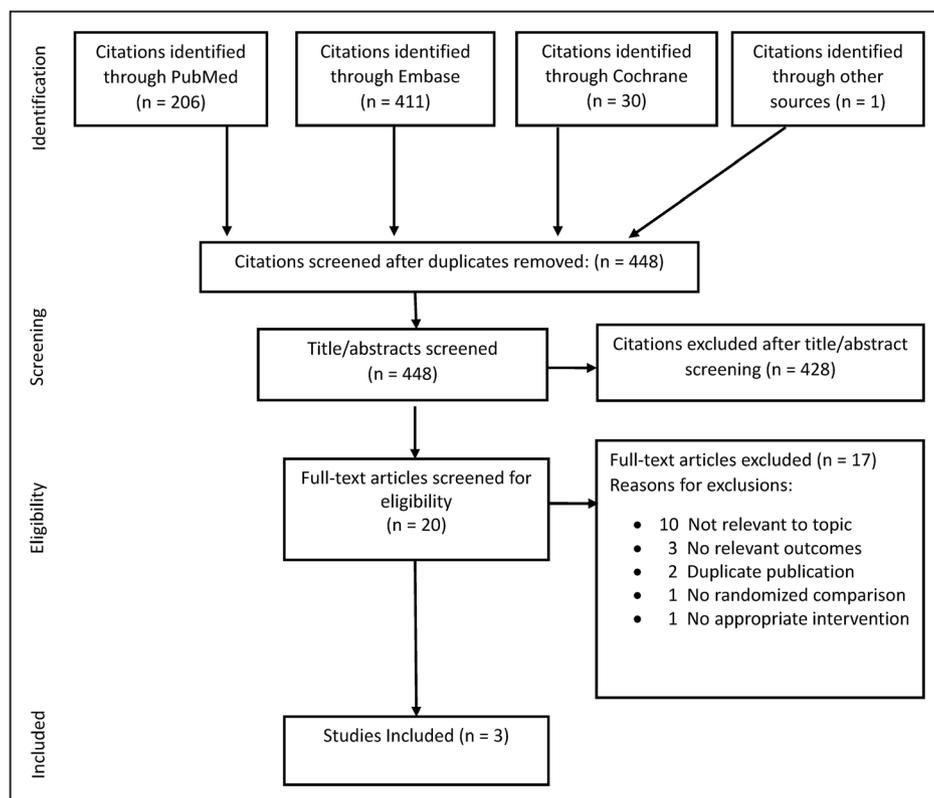
Hospitalized patients with stroke (either ischemic stroke or intracerebral hemorrhage)
Includes adults (age $\geq 18$ y)
Randomized comparison
Intervention was either a dysphagia screen, which could be the only intervention or only 1 component of a multifaceted intervention to improve stroke unit care, or a quality improvement intervention to improve screening rates; screening was defined as "a pass/fail procedure to identify individuals who require a comprehensive assessment of swallowing function or a referral for other professional and/or medical services." <sup>11</sup>
Comparator group was no screening, an alternative screening method, usual care, or a gold standard diagnostic method for aspiration (either speech language pathologist consultation or videofluoroscopy).
Reported $\geq 1$ of these outcomes: death, dependency, or pneumonia
Study published in 1975 or later

randomized to receive either a fever, sugar, and swallowing intervention designed to improve nursing adherence to evidence-based protocols or a comparator intervention consisting of an abridged version of existing guidelines. The Acute Screening of Swallow in Stroke or TIA [transient ischemic attack] tool was used as the dysphagia screen.<sup>16</sup> This tool uses patient symptoms and signs and a water swallow test to screen for aspiration risk. Nurses in the intervention stroke units attended an in-service training by a speech language pathologist and were required to pass a competency examination. They then applied the tool in clinical practice. The study quality was high, with the only risk for bias being that blinding of the intervention was not possible (Table 2). Compared

with patients treated in the control stroke units (n=451), those treated in the intervention stroke units (n=558) had a reduction in the composite outcome of death or dependency and better Short Form Health Survey mean scores (Table 3 provides details). However, there were no differences in mortality as a single outcome or the rate of aspiration pneumonia.

In another trial, 311 stroke patients referred for swallowing evaluation were randomized to either a standard evaluation or a standard evaluation plus the cough reflex test.<sup>14</sup> In the cough reflex test, nebulized citric acid was delivered by face mask, which normally induces a reflexive cough. If the test was failed, subsequent management was left to the treating physician. The study quality was generally high with low risk of bias (Table 2), with the exception that there was no blinding of either the study intervention or the study outcome assessment. Patients randomized to receive the cough reflex test had similar rates of confirmed pneumonia at 90 days compared with those who received standard evaluation (Table 3).

Finally, another trial randomly assigned wards in the same hospital to a stroke care pathway (1 ward) or conventional care (1 ward).<sup>15</sup> The stroke care pathway included a local institutionally developed swallow screen consisting of assessments of level of consciousness, strength of the patient's voice and cough, and ability to swallow sips of water and the local soft-texture foods khichri, kheer, or payasam (Kameshwar Prasad, MD, DM, MSc, written communication, September 12, 2017). The swallow screen was administered by a resident physician. The study quality was low (Table 2) with many risks for bias, including only 1 ward assigned to each study arm, nonrandomized admission of patients to either ward based on unclear

**Figure.** Flow diagram.

**Table 2. Risk for Bias**

Authors	Publication Year	Potential Causes of Bias						
		Was the Allocation Sequence Adequately Generated?	Was Allocation Adequately Concealed?	Was Knowledge of the Allocated Interventions Adequately Prevented During the Study? (Blinding)	Was Knowledge of the Allocated Interventions Adequately Prevented During the Outcome Assessment? (Blinding)	Were Incomplete Outcome Data Adequately Addressed?	Are Reports of the Study Free of Suggestion of Selective Outcome Reporting?	Was the Study Apparently Free of Other Problems That Could Put It at a Risk of Bias?
Middleton et al <sup>13</sup>	2011	Yes (low risk of bias)	Yes (low risk of bias)	No (high risk of bias)	Yes (low risk of bias)	Yes (low risk of bias)	Yes (low risk of bias)	Yes (low risk of bias)
Miles et al <sup>14</sup>	2013	Yes (low risk of bias)	Yes (low risk of bias)	No (high risk of bias)	No (high risk of bias)	Yes (low risk of bias)	Yes (low risk of bias)	Yes (low risk of bias)
Rai et al <sup>15</sup>	2016	No (high risk of bias)	No (high risk of bias)	No (high risk of bias)	No (high risk of bias)	Unclear risk of bias (insufficient information)	Yes (low risk of bias)	No high risk of bias*

Assessed with the Cochrane Risk of Bias Tool.<sup>12</sup>

\*Judged to be at high risk of bias because of a baseline imbalance in the proportion of hemorrhagic stroke patients, with a higher frequency of hemorrhagic stroke admissions to the ward randomized to usual care.

criteria, no blinding of the intervention or outcome assessments, inadequate information on the completeness of follow-up, and a baseline imbalance in the number with hemorrhagic stroke in each group. Patients in the unit with the stroke care pathway were less likely to require mechanical ventilation and had lower all-cause mortality at 90 days (Table 3).

### Conclusions

This systematic review found insufficient RCT data to show whether implementation of a specific dysphagia screening protocol reduces the risk of death or dependency after stroke.

Three eligible trials were identified.<sup>13–15</sup> Interpretation of 2 of the trials, including the largest highest-quality trial,<sup>13</sup> was confounded by other concurrent quality improvement interventions.<sup>13,15</sup> One trial showed no difference in the rates of pneumonia in patients randomized to receive the cough reflex test.<sup>14</sup> In addition, 1 trial was small, including only 2 randomized wards, thus limiting the ability to account for baseline differences, and was at high risk for bias according to most criteria of the Cochrane Risk of Bias tool (Table 2).<sup>15</sup> Because of the limited data available, no conclusions can be drawn about the clinical effectiveness of dysphagia screening protocols.

**Table 3. Summary of Eligible Studies**

Authors	Design	Size	Intervention	Selected Outcomes
Middleton et al <sup>13</sup>	Cluster RCT	19 Stroke units, 1126 patients	Intervention: fever, sugar, and swallowing intervention consisted of protocols, workshops, site visits, and e-mail/telephone support Nurses were trained to use ASSIST dysphagia screening tool via in-service training by a speech pathologist and were required to pass a competency examination. Comparator: abridged version of existing guidelines	Death and dependency (mRS score $\geq 2$ ): 42% (236 of 558) vs 58% (259 of 449) ( $P=0.002$ ) All-cause mortality: 3.7% (21 of 558) vs 5.3% (24 of 451) ( $P=0.36$ ) Aspiration pneumonia: 2.1% (13 of 603) vs 2.7% (13 of 483) ( $P=0.82$ )
Miles et al <sup>14</sup>	RCT	311 Patients	Intervention: clinical swallowing evaluation and cough reflex testing Comparator: clinical swallowing evaluation	Confirmed pneumonia: 26% (38 of 148) vs 21% (35 of 163) (adjusted OR 1.7; 95% CI, 0.9–3.0; $P=0.38$ ) All-cause mortality: 14% (20 of 148) vs 20% (32 of 163) (adjusted OR, 0.7; 95% CI, 0.4–1.3; $P=0.23$ )
Rai et al <sup>15</sup>	Cluster RCT	2 Wards, 162 patients	Intervention: stroke care pathway consisting of nurse education, care checklist, swallow assessment flowchart, swallow screen, and patient and caregiver education. The swallow screen was culturally adapted to local food habits and administered by a resident physician. Comparator: conventional care based on existing ward practices. Feeding started on the basis of physician judgment.	Aspiration pneumonia during hospital stay: 6.5% (5 of 77) vs 15.3% (13 of 85) (adjusted OR, 0.33; 95% CI, 0.09–1.22; $P=0.10$ ) Mechanical ventilation during hospital stay: 7.8% vs 17.6% (OR, 0.39; 95% CI, 0.14–1.07; $P=0.05$ ) All-cause mortality at 90 d: 7.8% (6 of 77) vs 20% (17 of 85) ( $P=0.02$ ) (adjusted OR, 0.33; 95% CI, 0.12–0.90; $P=0.03$ ) mRS score $\leq 2$ at 90 d: 57.1% (44 of 77) vs 57.6% (49 of 85) ( $P=NS$ )

ASSIST indicates Acute Screening of Swallow in Stroke or TIA [transient ischemic attack]; CI, confidence interval; mRS, modified Rankin Scale; NS, not significant; OR, odds ratio; and RCT, randomized controlled trial.

The largest, highest-quality study (QASC) showed that a combined quality improvement intervention to implement protocols for fever, glucose, and swallow screening reduced the risk of death or dependency. However, the independent effect of dysphagia screening could not be estimated because it was implemented as only 1 part of a combined multidomain stroke unit intervention. Although the rate of death or dependency in the multidomain stroke unit quality improvement intervention was lower than in the comparator condition, the rate of aspiration pneumonia did not differ, suggesting that mortality improvements were not the result of pneumonia prevention.

Managing dysphagia may be a promising avenue to improve stroke outcomes. However, patient selection for future trials of dysphagia screening protocols may benefit from a deeper understanding of the prevalence of aspiration and the association between severity of aspiration and the risk for clinical events such as pneumonia to allow screening to be targeted to individuals at risk. Furthermore, the clinical effectiveness of a dysphagia screening strategy will depend not only on the accuracy and reliability of the screening method but also on the effectiveness of the dysphagia management interventions that follow. A Cochrane review found evidence that acupuncture and behavioral interventions reduce the prevalence of dysphagia, but there was insufficient evidence to prove a reduction in death or dependency.<sup>17</sup>

To manage dysphagia, it must first be identified. By design, the ERC did not review evidence for the accuracy and reliability of different nurse-administered dysphagia screening protocols compared with gold standard assessments by a speech language pathologist, videofluoroscopy, or fiberoptic endoscopic evaluation. This was previously reviewed

systematically by Kertscher et al<sup>4</sup> in 2014, who found the best evidence in support of the volume-viscosity swallowing test, the Toronto Bedside Swallowing Screening Test, and the 3-oz water swallowing test but without sufficient comparative studies to identify the optimal screening test. A consensus group convened by the American Heart Association/American Stroke Association in 2013 recommended that an externally validated screening test should be chosen, but there was insufficient evidence for the superiority of any 1 test.<sup>11</sup> That group also pointed out that the absence of consensus for a single best screening method does not mean that no screening should be performed.<sup>11</sup> Our review complements this work by showing that no recently published RCTs have compared different dysphagia screening methods for their ability to reduce death, dependency, or pneumonia, except for 1 single-center RCT<sup>14</sup> that failed to find evidence that screening with the cough reflex test reduced rates of pneumonia or death.

The ERC identified a need for additional prospective studies to compare the validity, feasibility, and clinical effectiveness of different screening methods for dysphagia. Ideally, these studies would randomly assign patients to different screening methods, potentially using a cluster randomized design, with outcomes including accuracy of dysphagia detection and incidence of pneumonia, stroke-related disability, and death at 90 days. To minimize variation in treatment between randomized groups, the management of patients after screening should be done according to a standardized protocol. The information from such trials would help hospitals to select the most appropriate screening tools for their practice and would help support the validity of dysphagia screening as a performance measure for stroke quality improvement.

## Disclosures

### Writing Group Disclosures

Writing Group Member	Employment	Research Grant	Other Research Support	Speakers' Bureau/Honoraria	Expert Witness	Ownership Interest	Consultant/Advisory Board	Other
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Ketan R. Balsara	University of Connecticut	None	None	None	None	None	None	None
Lester Y. Leung	Tufts Medical Center	None	None	None	None	None	None	None
Judith H. Lichtman	Yale School of Public Health	None	None	None	None	None	None	None
Mathew J. Reeves	Michigan State University	None	None	None	None	None	None	None
Amytis Towfighi	University of Southern California	None	None	None	None	None	None	None
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Darin B. Zahuranec	University of Michigan	None	None	None	None	None	None	None

This table represents the relationships of writing group members that may be perceived as actual or reasonably perceived conflicts of interest as reported on the Disclosure Questionnaire, which all members of the writing group are required to complete and submit. A relationship is considered to be "significant" if (a) the person receives \$10 000 or more during any 12-month period, or 5% or more of the person's gross income; or (b) the person owns 5% or more of the voting stock or share of the entity, or owns \$10 000 or more of the fair market value of the entity. A relationship is considered to be "modest" if it is less than "significant" under the preceding definition.

## Reviewer Disclosures

Reviewer	Employment	Research Grant	Other Research Support	Speakers' Bureau/Honoraria	Expert Witness	Ownership Interest	Consultant/Advisory Board	Other
Argye E. Hillis	Johns Hopkins University	NIH (I am mentor on a K23 investigating dysphagia)*	None	None	None	None	None	None
Irene L. Katzan	Cleveland Clinic	Ohio Department of Health (Ohio Coverdell Stroke Quality Improvement Registry)†	None	None	None	None	None	None
Walter N. Kernan	Yale University	None	None	None	None	None	None	None

This table represents the relationships of reviewers that may be perceived as actual or reasonably perceived conflicts of interest as reported on the Disclosure Questionnaire, which all reviewers are required to complete and submit. A relationship is considered to be "significant" if (a) the person receives \$10,000 or more during any 12-month period, or 5% or more of the person's gross income; or (b) the person owns 5% or more of the voting stock or share of the entity, or owns \$10,000 or more of the fair market value of the entity. A relationship is considered to be "modest" if it is less than "significant" under the preceding definition.

\*Modest.

†Significant.

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