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Formal Dysphagia Screening Protocols Prevent Pneumonia

Judith A. Hinchey, MD; Timothy Shephard, RN, CN; Karen Furie, MD, MPH; Don Smith, MD; David Wang, DO; Sarah Tonn, MPH; for the Stroke Practice Improvement Network Investigators

Background—Pneumonia is an important complication of ischemic stroke and increases mortality 3-fold. Five guidelines recommend a dysphagia screen before oral intake. What constitutes an adequate dysphagia screen and which patients should receive it remain unclear.

Methods—Fifteen acute care institutions prospectively collected data on all admitted patients with acute ischemic stroke. Sites were required to collect data on demographics and 4 quality indicators. Optional data included stroke severity and complications. We measured adherence to a screen for dysphagia, the type of screen, and development of in-hospital pneumonia.

Results—Between December 2001 and January 2003, 2532 cases were collected. In-hospital complications were recorded on 2329 (92%) of cases. Stroke severity was captured on 1361 (54%). Adherence to a dysphagia screen was 61%. Six sites had a formal dysphagia screen, and their adherence rate was 78% compared with 57% at sites with no formal screen. The pneumonia rate at sites with a formal dysphagia screen was 2.4% versus 5.4% ($P=0.0016$) at sites with no formal screen. There was no difference in median stroke severity (5 versus 4; $P=0.84$) between the sites with and without a formal screen. A formal dysphagia screen prevented pneumonia even after adjusting for stroke severity.

Conclusions—A formal dysphagia screen is associated with a higher adherence rate to dysphagia screens and a significantly decreased risk of pneumonia. A formal screening protocol should be offered to all stroke patients, regardless of stroke severity. (*Stroke*. 2005;36:1972-1976.)

Key Words: complications ■ dysphagia ■ outcome assessment

Of the $\approx 700\,000$ Americans who experience a stroke annually, $>20\%$ die within the first year.¹ Of these strokes, nearly 13% develop pneumonia during their hospitalization. Approximately 35% of deaths that occur after an acute stroke are caused by pneumonia. Compared with poststroke survivors whose recovery is not complicated by pneumonia, there is a 3-fold increased risk of dying when diagnosed with pneumonia after an acute stroke.² It is believed that poststroke pneumonia is attributable to the aspiration of oral secretions or other oral intake in the presence of varying degrees of dysphagia. Given the knowledge that stroke patients presenting with dysphagia are at risk for pneumonia, pneumonia is a potentially preventable complication of stroke.³ However, adequate screening methods to identify those at risk and subsequent interventions to sufficiently prevent pneumonia in stroke survivors have not been identified.

Dysphagia is clinically present in $\approx 42\%$ to 67% of patients within the first 3 days of stroke onset.^{4,5} Although mild or moderate dysphagia often resolves within the first week after stroke onset, almost 50% of patients with dysphagia experi-

ence aspiration. Approximately one third of patients with dysphagia develop pneumonia requiring treatment.⁶

The latest American Stroke Association guideline for the early management of patients with ischemic stroke⁷ states that certain clinical characteristics may indicate that a patient is at higher risk for aspiration but also notes that the absence of deficits, such as an intact gag reflex, does not rule out the potential for aspiration. The guideline recommends that a swallow evaluation be performed in at-risk patients before any food or fluids are given orally. However, the definition of an “at-risk” patient remains vague, as does the type of swallowing evaluation to be performed. There is no consensus on which patients are at risk and which ones are not.

Once dysphagia is recognized, clinicians can intervene to prevent aspiration by using variations in food consistency and fluid viscosity. Implementation of compensatory swallowing techniques (chin tuck or head turn) is thought to reduce the risk of aspiration.⁸

In observational studies with historical controls, implementation of a dysphagia screening program has been shown to reduce the incidence of pneumonia.^{9,10} Despite the work by

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Odderson,⁹ and given the fact that an assessment of swallow before oral intake has been recommended in 5 practice guidelines for acute stroke care,¹¹ a clear, evidence-based recommendation for the application of a competent dysphagia screening tool, and to whom and when it should be applied, is not available.

This study is an effort to answer questions concerning the application of dysphagia screening tools and the prevention of pneumonia in acute stroke patients. This project examined whether a dysphagia screen was performed on each patient. It assessed the type of screen used, whether the screen was performed before oral intake, and the prevalence of pneumonia relative to the severity of deficits using the National Institutes of Health Stroke Scale (NIHSS).

Methods

The study was conducted using in-hospital data that were prospectively collected between December 2001 and January 31, 2003, as part of the Stroke Practice Improvement Network (SPIN) registry. This is part of a group-randomized, controlled, multicenter trial assessing the efficacy of a multimodal intervention aimed at increasing the adherence rates of 4 primary, in-hospital ischemic stroke process of care indicators.¹²

Participating Hospitals

The study was conducted at 15 healthcare institutions in North America. The 15 sites were chosen by an American Academy of Neurology Site Selection work group to collect prospective/concurrent in-hospital stroke care data as members of the SPIN registry. A variety of practice settings are represented. Three hospitals had <200 acute beds, 6 have 200 to 400 acute beds, and 6 had >400 acute beds. Other site characteristics included 4 urban academic hospitals, 2 academic affiliated community hospitals, and 9 community hospitals. A dedicated stroke unit was present in 73% (11 of 15) of hospitals, 93% (14 of 15) had stroke teams, and 100% had stroke pathways.

Subject Inclusion Criteria

Included in the study were all patients ≥ 18 years of age who were discharged with a diagnosis of acute ischemic stroke. The target population consists of all acute ischemic stroke patients under the care of neurologists either as consulting or attending physicians.

Data Collection

Patients with suspected stroke meeting the inclusion criteria were enrolled at the time of admission or when first evaluated by the study coordinator. Data were collected by the study coordinator and entered directly into a Web-based data collection system. Study coordinators either followed the patient during the hospital stay or returned to the hospital chart before discharge to collect any follow-up data or complications. Only events occurring in hospital were collected.

Required data collection included all information needed to determine adherence rates to 4 quality process of care indicators and patient demographic and discharge data. The inclusion and exclusion criteria for the dysphagia screening indicator are: number of patients screened for dysphagia before food and drink/number of patients, excluding in-hospital transfers. Optional data included in-hospital complications such as pneumonia and stroke severity on admission as measured by the NIHSS. Five sites did not collect data on in-hospital complications or stroke severity, and we excluded their data from the outcome assessment part of the project. Data from all the study sites were used to determine overall adherence rates to dysphagia screening and types of screens performed.

Data Definitions

A clinical data entry manual was developed to guide study coordinators during data collection and entry. The clinical data entry manual was developed by using extant definitions from the American Heart Association/American College of Cardiology and the Centers for Disease Control Nosocomial infection definitions.¹³ The definition of pneumonia includes either the clinical finding of rales or dullness to percussion and 1 of the following: purulent sputum, or isolation of the organism, or chest radiograph showing evidence of an infiltrate/consolidation/cavitation or pleural effusion and 1 of the following: purulent sputum or isolation of the agent or antibody evidence of an agent.¹⁴

Statistical Methods

Survey

A site inventory survey was developed to collect system tools (eg, preprinted stroke admission orders, dysphagia screening tools) if used at each site. Sites were specifically asked to outline the existing processes in place for each of the 4 primary indicators. We determined who had a formal dysphagia screening protocol on the basis of this inventory survey that was received from 100% of sites.

A formal screen was defined as a check sheet listing a process by which the patient is progressively assessed for previous risk factors of aspiration and current increased risk on the basis of clinical findings. All formal screens recommended nothing by mouth (NPO) status and further evaluation by a speech-language pathologist (or similarly trained professional) if any of these abnormalities existed and did not allow for participation in a water challenge. If the patient passed the initial portion of the screen, it was followed by a water challenge and observed. All screening tools described various abnormal consequences that could be observed.

Analytic Plan

Adherence rates between sites with formal dysphagia screening protocols and those without formal protocols were tested for differences in 2 proportions. Two logistic regression models were used to assess the degree of association between the type of dysphagia screen and NIHSS score on adherence and pneumonia rates. Odds ratios were used to describe the magnitude or a unit increase in an independent variable (ie, NIHSS score) and the odds of pneumonia, being screened, or adherence. The effects of a patient NPO status and mortality were also evaluated.

Power and Sample Size for Adherence Rates

Sample size calculations were derived to detect a 13% difference in adherence rates between the group of sites with a formal dysphagia screen and those without a formal dysphagia screen. This was based on the overall trial that expects an 11% to 13% increase in adherence for sites randomized to the multimodal intervention beyond sites only given continuous feedback and benchmarking.¹⁴ A type 1 error at 0.05 and statistical power of 80% yielded the need for a minimum of 50 patients at each hospital.¹⁵

Data Validation

Reliability and Sampling Bias

Medical record abstraction performed by qualified abstractors assessed reliability of the data and sampling bias related to the inclusion and exclusion criteria and patient demographics. Sample size calculations for assessing reliability and sampling bias resulted in 95 charts across sites (15% or a minimum of 10 charts per site). A randomization scheme was used to select cases for review. These records were de-identified at the site in accordance with Health Insurance Portability and Accountability Act and local requirements.

Measures of agreement such as the κ -statistic for categorical data and appropriate correlation coefficients for continuous data were used to evaluate the reliability of the concurrent data collection. Point estimates and 95% CIs were generated for correlation coefficients, κ -values, and sampling bias results.

TABLE 1. Patient Characteristics

	Overall	Formal Protocol at Site n=742	Informal Protocol at Site n=1790	P Value
Age, y (SD)	70.5 (14)	68.7 (15)	71.3 (14)	0.0001
Male sex, no. (%)	1262 (50)	374 (50)	891 (50)	0.77
White, %	82	64	90	0.0001
Black, %	9.5	19	5.4	0.0001
Baseline NIHSS (mean)	7.2 (CI 6.8–7.5)	7.1 (7)	7.2 (7)	0.82
Median NIHSS		5	4	0.82
NIHSS categories				0.65
Mild, NIHSS 0–8, %	70	70	69	
Moderate, NIHSS 9–16, %	17	18	16	
Severe, NIHSS >17, %	14	12.5	14	
Dysphagia adherence, %	63	78	56	<0.0001
Pneumonia, %	4.5	2.4	5.3	0.0016
Discharged alive, %	94	96	93	0.013

Concurrent Data Quality and Capture Rate

Data quality measures the percent of data that were missing from either concurrent or retrospective data collection. Sample size estimates resulted in the need for 84 cases in concurrent and retrospective samples. Differences in percentages of missing data between concurrent and retrospective rates were tested using a test of significance for proportions on 2 independent samples.

Results

Between December 1, 2001, and January 31, 2003, 2532 cases were included. In-hospital complications were recorded on 2329 (92%). Stroke severity was captured on 1361 (54%). The average age was 70, and 50% were males (for patient characteristics, see Table 1). Dysphagia screens were performed before oral intake in 61% (95% CI, 50 to 72), and the range at individual sites was 22% to 100%. The overall pneumonia rate was 4.7%. The overall in-hospital mortality rate was 5.9%. The mortality rate in those patients who developed pneumonia was 21% versus 4.8% in those without pneumonia ($P=0.0001$).

Validation of Data

A total of 115 charts were examined for reliability, sampling bias, and capture rates. Overall reliability was good ($\kappa=0.68$). Specific data elements that had poor agreement ($\kappa<0.5$) were: onset time, arrival data, and dysphagia screen before oral intake. Percentages of agreement for whether a dysphagia screen was performed, what type of screen, and whether the screen was performed before oral (PO) intake were 76%, 70%, and 69%, respectively. There was no introduction of sampling bias after comparing patient demographics. Prospectively, there was a 100% capture rate (forms could not be locked unless all required items were complete). Retrospectively, time of stroke symptom onset was the least found data element (67%). Dysphagia screen and type of dysphagia screen were documented in 96% of cases. Whether the screen was performed before oral intake was documented in 75% of cases.

Screen

A water swallow test was the documented screen in 37% of cases. The next most common screen was a physical exami-

nation (21%), although having a speech therapist perform either a bedside or formal examination occurred in 22%. Table 2 lists the common screens and their frequencies. When patients were kept nothing by mouth (NPO) through their whole hospital stay, sites were given credit for having performed a screen before PO intake.

Six sites had a formal dysphagia screening protocol consisting of the Burke water swallow test or a variant developed de novo by the site.¹⁶ Formal dysphagia screens were present in 2 of the academic hospitals (both with stroke units), 1 of the academic-affiliated hospitals (included a stroke unit), and 3 of the community hospitals (none had a dedicated stroke unit). Six hospitals with dedicated stroke units did not have a formal screening protocol in place.

Adherence Rates

Six of the 15 sites had a formal dysphagia screening protocol, and their adherence rate was significantly higher: at 78% (580 of 742) versus 56% (1014 of 1779), $P<0.0001$, in those without.

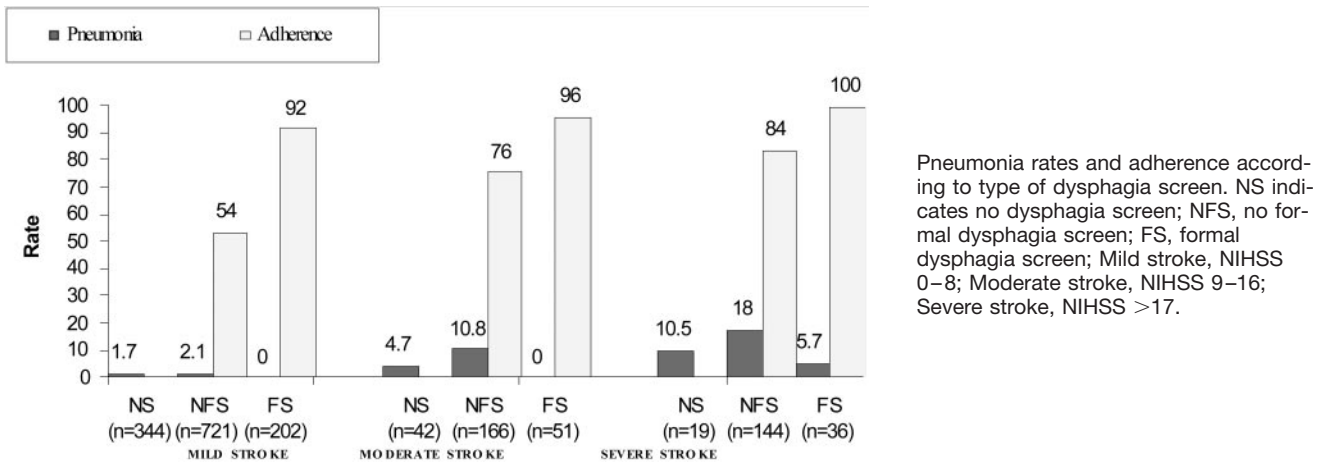
In sites that had no formal protocol, a screen for dysphagia was more common among those with a higher NIHSS ($P<0.0001$). The odds of being screened increased by 8% (CI, 6% to 10%) for every 1-point increase in NIHSS score (Figure). There was no significant relationship between screening and NIHSS score at sites with a formal protocol. There was no association between race and adherence.

Pneumonia

In all sites, the pneumonia rate was significantly higher in those who had any screen for dysphagia versus those who did

TABLE 2. Other Types of Dysphagia Screen

Speech therapy	21%
Clinical examination	20%
Bedside evaluation	12%
Modified diet	3%
Nothing by mouth	4.6%



not: 5.7% (85 of 1505) versus 2.3% (19 of 824) $P<0.0001$. However, in sites with a formal dysphagia screening protocol, the pneumonia rates were significantly lower than those of sites with no formal written protocol: 2.4% (17 of 704) versus 5.4% (87 of 1626); $P=0.0016$. The unadjusted odds ratio for a formal screening program was 0.11 (0.03 to 0.48).

NIHSS and age were important predictors of development of pneumonia. Race was not a predictor of pneumonia. For every 1-point increase in the NIHSS score, the odds of pneumonia increased by 12%. The median NIHSS in those who developed pneumonia was also higher than those who did not (14 versus 4; $P<0.0001$). There was no difference in median stroke severity as measured by the NIHSS between those sites that had a formal protocol versus sites that did not (5 versus 4; $P=0.82$).

For age, every 1-year increase increased the odds of pneumonia by 2% ($P=0.002$). But age was not an independent predictor of pneumonia in a multiregression model that included stroke severity. Having a formal screening protocol decreased the odds of pneumonia 3-fold even after adjusting for stroke severity, with an adjusted odds ratio of 0.10 (CI, 0.03 to 0.45).

Death

For those who develop pneumonia, the odds of dying increased 5.4-fold (95% CI, 3.2 to 9.0), with 21% dying compared with 4.8%. The median NIHSS score in patients who died was significantly higher (17 versus 4; $P<0.0001$). For every 1-point increase in the NIHSS, the odds of dying increased by 16%.

NPO

Of the 4.6% ($n=117$) of patients kept NPO, 22.5% developed pneumonia. The median NIHSS of those kept NPO was 19 ($P<0.0001$). The mortality rate for those kept NPO was 47% ($P<0.0001$).

Length of Stay

Median length of stay (LOS) in cases that adhered to a screen for dysphagia was 5 days versus 4 days for cases that did not adhere to the indicator. Median LOS in patients kept NPO was 6 versus 5 days for those not kept NPO, and the mean was 10 versus 6 days. Median LOS in those who developed

pneumonia was 14 days versus 5 days in those who did not develop pneumonia ($P<0.0001$).

Discussion

A formal dysphagia screening protocol decreases the incidence of pneumonia in patients hospitalized for ischemic stroke. Using a formal protocol (check sheet and water swallow performed on all stroke admissions) decreases the risk of pneumonia by 3-fold. Having a formal screening process was associated with increased adherence to completing the screen before oral intake. Formal screens were done in patients across the entire spectrum of stroke severity (as measured by the NIHSS) as opposed to other “informal” screens being done on the patients with higher stroke severity (Figure). This suggests that hospitals with a formal program include screening on all patients, whereas other hospitals may only think of performing a screen on patients who, by intuitive criteria, are at higher risk of pneumonia. This is similar to what Odderson et al found when they implemented a clinical pathway with a screening program at their institution.⁹ The pneumonia rate went from 6.7% in the year before the screen to 4.1% (a relative risk reduction of 39%) to 0 cases of pneumonia in the second year (relative risk reduction, 100%). Others have also implemented dysphagia screening programs with similar results.⁴

Although Agency for Healthcare Research and Quality has not recommended a single screening modality and notes a lack of consensus on which screening procedure or diagnostic test to use in identifying at-risk patients, it acknowledges that implementation of a dysphagia management program for stroke patients is recommended.⁶ We are not recommending which dysphagia screening protocol to use. Our study sites have modified existing protocols, thus invalidating any testing for validity or reliability of these tools, but we do recommend a formal protocol be implemented. If instituting a formal dysphagia screening protocol prevented just one half of the poststroke pneumonias, it could save nearly 8300 lives and prevent nearly 40 000 pneumonias per year (based on 700 000 strokes per year).

Patients who are kept NPO for their whole hospital stay still have a very high pneumonia and mortality rate. Other variables need to be considered to decrease pneumonia rates in this subpopulation. Further study may include intervention

with extant devices or procedures. Use of inspiratory spirometers is done in all surgical patients but rarely given to stroke patients. Timing of percutaneous gastrostomy tubes and the use of dobhoff versus nasogastric tubes with larger diameters may also be important but need further study.¹⁷

This study is limited in that the design was not specific for a randomized controlled trial of dysphagia screening protocols versus no protocols and was done as a secondary analysis. Discrepancies in age and race were found between the 2 groups, and although we could not prove that this impacted the development of pneumonia, it may be a marker for other variances at the sites that were not measured. Sites with a protocol may have other characteristics that also impact on the development of pneumonia that were not assessed. There may be other processes of care that impact outcome that are more important than the dysphagia screen itself and will require further study.

In addition, the data validation component of this study illustrates areas of poor agreement between prospective and retrospective data, specifically for the variables of type of screen and screening performed before oral intake. This is attributable in part to the multiple assessment methods used by sites as “screens” such as the initial clinical/cranial nerve examination and the formal or informal dysphagia screens. On retrospective review, it may be difficult for abstractors to correctly identify the actual “screen” and at what point the screen was performed. This highlights the disadvantage of retrospective data collection for quality improvement research. Repeated efforts have demonstrated the inability of retrospective data to accurately reflect the care delivery process, and the validation component of this study supports such conclusions.¹⁸

We have shown that sites with a formal dysphagia screening program have better adherence to dysphagia screens and a significantly decreased rate of pneumonia. By implementing a similar protocol at other hospitals, we may be able to improve clinical and fiscal outcomes.

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