

# Dysphagia therapy following stroke: A controlled trial

K.L. DePippo, MS; M.A. Holas, MS; M.J. Reding, MD; F.S. Mandel, PhD; and M.L. Lesser, PhD

**Article abstract**—*Objective:* To determine the effect of graded levels of intervention by a dysphagia therapist on the occurrence of pneumonia, dehydration, calorie-nitrogen deficit, recurrent upper airway obstruction, and death following stroke. *Design:* A randomized control trial. *Setting:* Inpatient stroke rehabilitation unit. *Patients:* All patients met the following eligibility criteria: (1) stroke defined by clinical history and neurologic examination with compatible CT or MRI, (2) ages 20 to 90 years inclusive, (3) no known history of significant oral or pharyngeal anomaly, (4) laboratory values below end point criteria, (5) failure on the Burke Dysphagia Screening Test, and (6) modified barium swallow evaluation evidence of dysphagia (patients who aspirated  $\geq 50\%$  of all consistencies presented, even using compensatory swallowing techniques, were excluded). Of 123 eligible patients, eight refused study participation. One hundred fifteen patients were randomized. *Interventions:* Three graded levels of dysphagia therapist control of diet consistency and reinforcement of compensatory swallowing techniques were provided during the inpatient rehabilitation stay. *Main outcome measures:* Pneumonia, dehydration, calorie-nitrogen deficit, recurrent upper airway obstruction, and death. *Results:* The log rank statistic showed no significant difference between the three treatment groups for the distribution of time until end point during the inpatient stay or to 1 year post-stroke. *Conclusion:* Limited patient and family instruction regarding use of diet modification and compensatory swallowing techniques during inpatient rehabilitation is as effective as therapist control of diet consistency and daily rehearsal of compensatory swallowing techniques for the prevention of medical complications associated with dysphagia following stroke.

NEUROLOGY 1994;44:1655-1660

The frequency of dysphagia in patients with stroke is 13% for patients with unilateral hemispheric lesions and 71% for patients with bilateral brainstem lesions.<sup>1</sup> Dysphagia is most accurately assessed by videofluoroscopic modified barium swallow (MBS) evaluation. The MBS evaluation documents dysphagia and aspiration, and is the basis for developing an individualized dysphagia treatment plan. During the standard MBS protocol, different dietary textures (ie, liquids, puree, semisolids) are administered to determine which diet consistencies and amounts are easiest and safest for the patient to swallow.<sup>2-5</sup> In addition, compensatory swallowing techniques (eg, chin tuck or head turn) can be attempted to reduce aspiration or to improve swallowing efficiency.<sup>6,7</sup>

Most dysphagia treatment plans include the diet consistency and compensatory swallowing techniques found to be effective during the MBS evaluation.<sup>8,9</sup> The efficacy of these widely used dysphagia management techniques in patients with stroke has not been critically assessed. Logemann and Kahrilas<sup>10</sup> reported that a patient with a medullary infarct resumed total oral feeding at 50 months post-stroke by using a combination of diet modification and compensatory swallowing techniques.

Horner et al<sup>11,12</sup> studied the outcome of patients with dysphagia following stroke and reported that most patients studied were able to resume or maintain oral feeding after initiation of programs that included diet modification and compensatory swallowing techniques.

The primary goals of dysphagia therapy are to establish optimal nutritional status and to eliminate or reduce the risk of developing medical complications associated with dysphagia. Several authors<sup>13-15</sup> have studied the effect of various management techniques on dysphagia-related medical complications in patients with dysphagia due to a variety of causes. The efficacy of diet alteration and use of compensatory swallowing techniques for the treatment of dysphagia following stroke is still unknown.

This paper reports the results of a prospective 3-year study designed to investigate the effect of graded levels of therapist control of diet consistency and reinforcement of compensatory swallowing techniques on the occurrence of pneumonia, dehydration, calorie-nitrogen deficit, recurrent upper airway obstruction, and death following stroke. A no-treatment group was not used due to ethical considerations. A dose-response design was used as an alternative, with intensity of therapist intervention evaluated.

From the Cornell University Medical College at the Burke Rehabilitation Hospital (K.L. DePippo and M.A. Holas, and Dr. Reding), White Plains, NY; and North Shore University Hospital-Cornell University Medical College (Drs. Mandel and Lesser), Manhasset, NY.

Supported by US Public Health Service grant No. 1-RO1-DC00885.

Received October 8, 1993. Accepted in final form March 7, 1994.

Address correspondence and reprint requests to Kathleen L. DePippo, 785 Mamaroneck Avenue, White Plains, NY 10605.

**Methods.** All patients admitted to an inpatient rehabilitation unit over 24 months and meeting the following criteria were eligible for participation: (1) stroke defined by clinical history and neurologic examination with compatible CT or MRI, (2) ages 20 to 90 years inclusive, (3) no known history of significant oral or pharyngeal anomaly, (4) laboratory values below end point criteria, (5) failure on the Burke Dysphagia Screening Test,<sup>16,17</sup> and (6) MBS evidence of dysphagia.

The MBS evaluation consisted of 5 ml thin barium liquid, 5 ml thick barium liquid, 5 ml barium-impregnated pudding, one-fourth of a cookie coated with barium, 20 ml thin barium liquid to be taken in one swallow, and 30 ml thin barium liquid to be taken in consecutive swallows. Patients were seated upright and viewed in the lateral position and then the anterior-posterior position for one 5 ml thin barium liquid swallow. Compensatory swallowing techniques such as chin tuck, multiple swallows, or liquid assist were attempted to determine their effectiveness for improving swallowing efficiency or reducing aspiration. Testing was aborted if the clinician deemed it unsafe to proceed from one bolus to another. The fluoroscopic studies were recorded with a videocassette recorder with a video-counter timer (Panasonic AG-6200, Matsushita Audio-Video Systems, Osaka, Japan) and viewed by two speech-language pathologists who determined the presence or absence of dysphagia. The occurrence of aspiration, timing of aspiration, and consistency of test material aspirated were recorded. The results of all compensatory swallowing techniques attempted were also recorded.

Patients who demonstrated videofluoroscopic evidence of dysphagia were eligible for study participation. Patients who demonstrated severe dysphagia, characterized by aspiration of  $\geq 50\%$  of all consistencies presented and continued aspiration of  $\geq 50\%$  following use of compensatory swallowing techniques, were deemed unsafe oral feeders and were not eligible for participation. Currently, there are no published criteria, based on the results of MBS evaluation, that define which patients are safe oral feeders. The use of the 50% aspiration criteria was based on our clinical experience.

Eligible patients or next of kin, or both, were informed of the nature of the investigation and were asked to give informed consent for participation. Those agreeing to participate were randomized into one of three dysphagia treatment groups (A, B, or C) representing graded levels of therapist control of diet consistency and reinforcement of compensatory swallowing techniques. Randomization was controlled by the Division of Biostatistics at North Shore University Hospital-Cornell University Medical College, Manhasset, NY, utilizing a permuted-blocks method.

Group A received one formal dysphagia treatment session, attended by the patient and relevant family members, to discuss the results of the MBS evaluation. The dysphagia therapist recommended an appropriate diet consistency based upon the results of the MBS. The patient and/or family members were then asked to choose a diet consistency they felt was most appropriate for them. They were given the option of selecting either a regular diet or one of four graded levels of diets designed for patients with dysphagia, and with all-liquid consistencies or with thickened liquids only. The patient or family also had the freedom to change the diet throughout the course of the rehabilitation stay. During the initial session, recommendations and training in the use of appropriate compensatory swallowing techniques found to improve swallowing during the MBS were given, but there

was no daily reinforcement of the techniques by a dysphagia therapist. If the patient or family requested additional rehearsal of techniques during the rehabilitation stay, it was provided. Group A therefore represented patients managed by diet and compensatory swallowing technique recommendations alone.

Group B received the diagnostic results and training in the use of compensatory swallowing techniques in a formal dysphagia treatment session, as did the patients in group A. Group B patients did not, however, choose their own diet. A dysphagia therapist prescribed a diet based on the results of the MBS evaluation. Patients in this group were reevaluated by the dysphagia therapist every other week for the need to change the prescribed diet consistency. In questionable cases, a repeat MBS was performed. Group B represented patients managed by a therapist-prescribed diet and compensatory swallowing technique recommendations.

Group C received the same formal dysphagia treatment session as did patients in groups A and B. The dysphagia therapist prescribed and controlled the consistency of the diet as for patients in group B. Patients in group C, however, were seen daily in a mealtime dysphagia management group where additional instructions and reinforcement of compensatory swallowing techniques were given. Group C therefore represented the most active therapist intervention group, in which the dysphagia therapist prescribed and controlled the diet and provided daily reinforcement of the recommended compensatory swallowing techniques.

All patients received the diet and compensatory swallowing technique recommendations in written form for the patient's or family members' future reference. In addition, a list of all available diet options was provided.

Biweekly monitoring sessions were conducted for all study participants during the inpatient stay to record whether patients were using the compensatory swallowing techniques recommended. Patients were scored as either "independent" or "not independent" in the use of each prescribed technique. All records of the biweekly observations were compiled at discharge, and the percentage of time each patient used the techniques was calculated. "Independent" was defined as a percent score  $\geq 75\%$ , and "not independent" was defined as a score  $< 75\%$ .

Study end points were as follows: pneumonia, dehydration, calorie-nitrogen deficit, recurrent upper airway obstruction, and death. Routine bloodwork, urinalysis, and medical chart review were obtained every other week to monitor the occurrence of end point variables.

Pneumonia was diagnosed if a patient had chest x-ray evidence of pneumonia or three or more of the following features: (1) sustained febrile illness  $> 100^\circ\text{F}$ , (2) presence of rales or rhonchi on chest auscultation, (3) drop in the arterial  $\text{Po}_2 > 10$  torr compared with baseline values, (4) sputum Gram's stain showing significant number of leukocytes, and (5) sputum culture showing respiratory pathogen. Dehydration was defined as serum sodium  $> 145$  or BUN  $> 50$  not due to primary renal insufficiency or the use of diuretics. Calorie-nitrogen deficit was defined as serum albumin  $< 2.5$  or sustained ketonuria without glycosuria over 2 weeks. Recurrent upper airway obstruction was documented if the patient required the Heimlich maneuver on two or more occasions.

Patients randomized into the study were followed for the duration of their inpatient stay and for 1 year post-stroke. If a study end point was reached during the inpatient stay, patients were dropped from their randomization group and medical intervention was initiated to ad-

**Table 1. Demographic features of the study population (N = 115)**

	Group A (N = 38)	Group B (N = 38)	Group C (N = 39)
Age (yr)*	76 (66.0-80.0)	74.5 (64.0-80.0)	73 (66.0-80.0)
Male/Female	22/16	19/19	27/12
Site of lesion			
Right hemisphere	11	14	11
Left hemisphere	12	15	11
Other	15	9	17
Mini-Mental State score†	16 ± 12	17 ± 10	18 ± 10
Barthel-ADL Mobility scores†	37 ± 23	48 ± 20	46 ± 38
Interval post-stroke to randomization (wk)*	4.6 (3.6-6.1)	4.5 (3.4-5.6)	4.9 (3.7-6.6)
Interval randomization to discharge (mo)*	2.1 (1.5-2.8)	2 (1.0-2.6)	1.7 (1.0-2.2)

\* Median (interquartile range).  
 † Mean ± SD.

No significant difference between the groups for any demographic feature.

dress the problem. Patients then received a therapist-controlled diet and daily reinforcement of compensatory swallowing techniques, which was current protocol for dysphagic patients at this facility. Patients did not re-enter the treatment protocol. Outcome variables were assessed by the "intent-to-treat" principle, which requires that all patients be analyzed as randomized.

Patients were assessed for the extent of motor, somatosensory, and homonymous visual deficits at the time of rehabilitation hospital admission, using a previously published protocol.<sup>18</sup> The Mini-Mental State Examination (MMSE) was used to assess cognition.<sup>19</sup> Functional abilities were assessed using the Barthel-ADL Mobility scale.<sup>20</sup>

The three treatment groups were examined for comparability of the demographic variables. The distribution of age was compared with the Kruskal-Wallis test. Distributions of sex, site of lesion, and stroke type were compared using the chi-square test for proportions (or Fisher's exact test, as appropriate). The distributions of admission MMSE scores and admission Barthel scores were compared using ANOVA. The distributions of time from stroke to randomization, time from randomization to discharge, and time until any event were estimated using the Kaplan-Meier product-limit method and were compared using the log rank test. Chi-square tests for proportions were used to compare the frequency of MBS-based abnormalities among the three treatment groups and the development of any end point. Chi-square tests were also used to compare the rates of use of compensatory swallowing techniques among the three treatment groups and the development of any end point. A Cox regression model was used to compare the distribution of time until the development of any end point and its relation to the three treatment groups and the MBS-based variables.

Data management and statistical analyses were performed using SAS (SAS Institute, Cary, NC).

Follow-up information regarding the development of pneumonia, dehydration, and death was collected by telephone interview with the patient or next of kin at 3, 6, and 12 months post-stroke for all study participants. Medical complications occurring after discharge from the inpatient unit were scored based on personal accounts, since laboratory data were unavailable to us.

**Table 2. Number of patients meeting end point criteria during the inpatient rehabilitation stay**

	Group A (N = 38)	Group B (N = 38)	Group C (N = 39)
Any end point*	6	7	5
Pneumonia	1	5	2
Dehydration	3	0	1
Calorie-nitrogen deficit	2	2	3
Recurrent upper airway obstruction	1	0	0
Death	0	0	0

Log rank test:  $p = ns$ .  
 \* Patients may have reached more than one study end point.

**Results.** A total of 123 patients were eligible for participation in the study protocol. Eight refused participation. One hundred fifteen patients were randomized a median of 4.57 (interquartile range, 3.57 to 6.14) weeks post-stroke. One patient dropped out of the treatment protocol. Demographic features of the study population by treatment group are listed in table 1. There was no significant difference between the groups in age, male:female ratio, lesion location, admission MMSE score, admission Barthel-ADL Mobility score, interval from stroke to randomization, or interval from randomization to discharge. The distributions of stroke type were also similar across the three treatment groups.

A total of 18 patients reached one or more of the study end points during the inpatient stay: six (16%) in group A, seven (18%) in group B, and five (13%) in group C (table 2). The log rank statistic showed no significant difference between the three groups for the distribution of time to end point. When data were analyzed for each individual end point, the log rank statistic showed no significant difference between the groups for time until pneumonia, dehydration, or calorie-nitrogen deficit. Only one instance of recurrent upper airway obstruction occurred and no deaths occurred; therefore, no individual analyses were performed on these two end points.

Time until end point analyses incorporating follow-up information for pneumonia, dehydration, and death were performed. There was no significant difference between the groups for the occurrence of medical complications when analyzed collectively (figure). There was also no significant difference in the occurrence of the individual end points of dehydration or death. There was a significant difference in time until pneumonia between the three treatment groups (log rank test,  $p = 0.03$ ). Pairwise comparisons determined that the significance was between groups A and B; patients in treatment group B tended to develop pneumonia

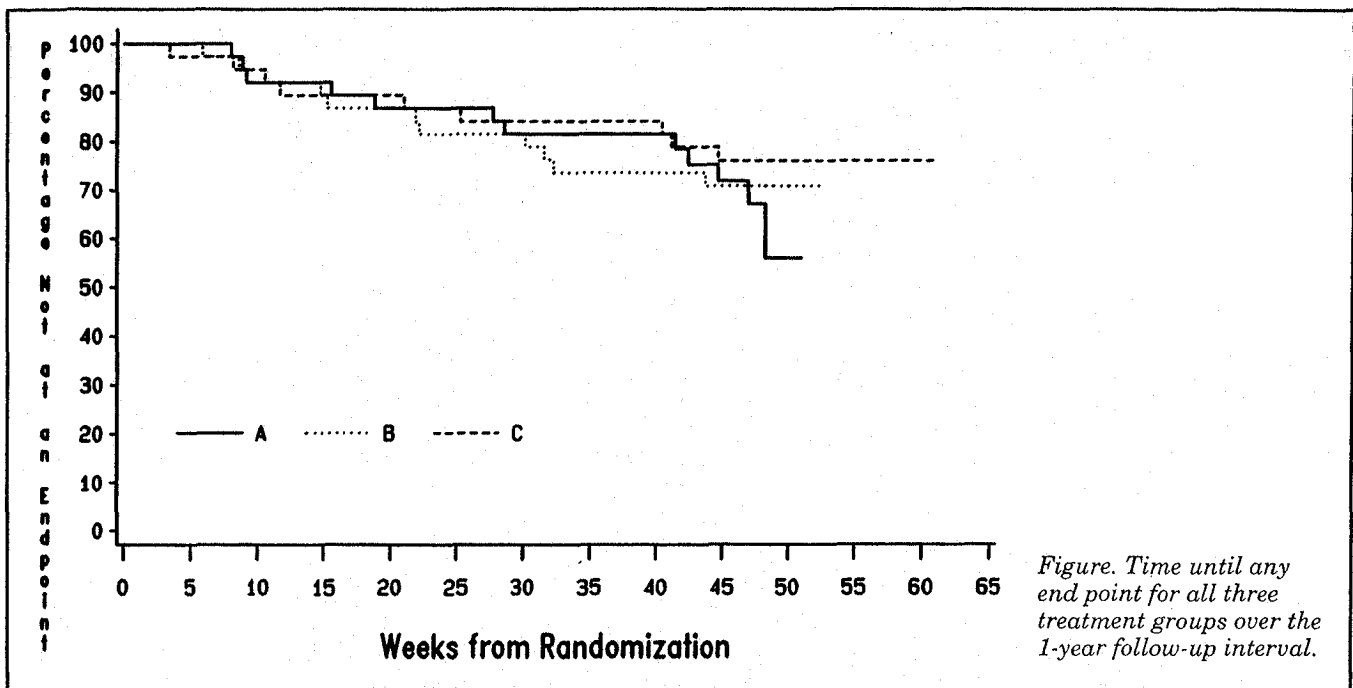


Figure. Time until any end point for all three treatment groups over the 1-year follow-up interval.

sooner during the studied time interval than those in treatment group A.

Outcome variables were also analyzed for patients grouped by stroke type (motor, motor/sensory, motor/sensory/vision, other), lesion location, Barthel scores (<41, 41 to 60, and >60), and admission MMSE scores (<25 and  $\geq$ 25). There was no significant difference in the occurrence of end points for patients grouped by any of these variables.

Eight patients were discharged before the first scheduled biweekly observation. Therefore, 107 patients had biweekly swallowing observations completed and were included in all analyses of compensatory swallowing techniques. Thirty-seven percent of patients who received daily reinforcement of compensatory swallowing techniques (group C) used the techniques independently ( $\geq$ 75% of the time) by discharge compared with 19% of patients in groups A and B (chi-square,  $p = 0.08$ ). There was no significant difference in the occurrence of any of the medical complications for patients who used the techniques independently compared with those who did not, regardless of treatment group. Due to the wide range of variability in independence in the use of the techniques, the data were also analyzed by quartiles. There was no significant difference in time until end point when use of compensatory swallowing techniques was scored as 0 to 24%, 25 to 49%, 50 to 74%, and 75 to 100%.

Information from the videofluoroscopic examination was recorded and analyzed to determine if more intensive treatment was effective for patients with more severe dysphagia, defined by presence of aspiration, consistency of material aspirated, and timing of aspiration. Cox regression analyses revealed that there was no significant difference between the three treatment groups after adjustment

for these three MBS-based variables.

Secondary analyses were conducted to determine whether the occurrence of end points correlated with the presence, consistency, or timing of aspiration independent of treatment group. Patients who aspirated tended to develop pneumonia sooner than those who did not (log rank test,  $p = 0.02$ ). Patients who aspirated thick liquids or more solid test material tended to develop pneumonia sooner than those who either aspirated thin liquids only or did not aspirate (log rank test,  $p = 0.05$ ). In addition, patients who aspirated after the swallow tended to develop pneumonia sooner than those who either aspirated before or during the swallow or did not aspirate (log rank test,  $p = 0.03$ ).

There was no correlation between the presence of aspiration, consistency of material aspirated, or timing of aspiration and the development of dehydration or calorie-nitrogen deficit for the study population as a whole or when categorized by treatment group.

**Discussion.** Our goal was to determine the effect of graded levels of therapist intervention on the medical complications associated with dysphagia: pneumonia, dehydration, calorie-nitrogen deficit, recurrent upper airway obstruction, and death. Our results showed that intensity of treatment using diet alteration and compensatory swallowing techniques did not affect the development of these complications.

During this investigation, only 15% of patients developed any of the five target medical complications during their inpatient stay. The small number of dysphagia-related medical complications may be due to all patients having received some level of treatment. There are no published studies

documenting an increased risk for these medical complications in patients with MBS-based evidence of dysphagia versus those without dysphagia with which to compare our data. Only a randomized, controlled trial, including a no-treatment group, could determine whether a specific dysphagia treatment program reduces the risk of developing medical complications.

Time until end point analyses incorporating follow-up data showed that patients in group B tended to develop pneumonia sooner than those in group A. This would imply that therapist control of diet consistency is detrimental. This is counterintuitive and inconsistent with a dose-response effect and may therefore be due to variables not controlled for in this study.

Most dysphagia management programs involve training in the use of compensatory swallowing techniques (ie, chin tuck, multiple swallows, liquid assist). We found that patients who received daily reinforcement of compensatory swallowing techniques were not significantly more independent in the use of these techniques by discharge than were patients receiving only limited instruction. This may be because a majority of our patients also had language or cognitive deficits that might have impaired their ability to learn and implement the techniques independently regardless of daily reinforcement. There was a significant difference in MMSE scores for patients grouped according to their ability to independently use the prescribed compensatory swallowing techniques. Patients with MMSE scores  $\geq 25$  were more likely to use strategies independently than those with MMSE scores  $< 25$  (chi-square,  $p = 0.02$ ).

When we analyzed the data regardless of treatment group, we found that patients who used the prescribed compensatory swallowing techniques independently had a risk of developing medical complications similar to that of patients who did not. Although the compensatory swallowing techniques recommended were shown on the MBS evaluation to decrease aspiration or increase swallowing efficiency, the use of the techniques did not reduce dysphagia-related medical complications.

Previous retrospective studies<sup>21</sup> have shown that MBS evidence of aspiration and aspiration of thick liquids or more solid test material are associated with an increased risk of developing pneumonia. In the present prospective study, we also found a significant relationship between these two variables and the development of pneumonia. In addition, a significant relationship was found between the timing of aspiration and the development of pneumonia. There is a correlation between timing of aspiration and death,<sup>22</sup> but no published studies have reported a correlation between timing of aspiration and the development of pneumonia. There was no significant difference in the occurrence of pneumonia between the three treatment groups when categorized by these three MBS-based variables (aspiration, consistency aspirated, and timing of aspiration).

Of all patients evaluated during the 2-year accrual period, only two were ineligible for participation due to the severity of their dysphagia (aspiration of  $\geq 50\%$  of all consistencies presented using compensatory swallowing techniques). In addition, 93% of eligible patients agreed to randomization in the study. Therefore, we believe that our patients were representative of dysphagic patients typical for an inpatient stroke rehabilitation unit and that our results are applicable to similar rehabilitation settings.

We found that limited patient and family instruction concerning diet modifications and compensatory swallowing techniques was as effective as dysphagia-therapist control of the diet and daily rehearsal of compensatory swallowing techniques for the prevention of dysphagia-related medical complications following stroke. Other groups with stroke, such as those in an acute-care hospital or those with severe dysphagia requiring non-oral feeding, may yet be shown to benefit from intensive dysphagia management programs.

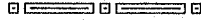
The true efficacy of dysphagia management techniques will be determined only by use of a no-treatment group, a design deemed unethical when this study was initiated.

As a result of this investigation, we advocate MBS-based diet and compensatory swallowing technique recommendations (group A-type therapy) for the treatment of dysphagia in the subacute phase post-stroke.


## References

1. Kuhlemeier K, Rieve J, Kirby N, Siebens A. Clinical correlates of dysphagia in stroke patients [abstract]. *Arch Phys Med Rehabil* 1989;70:A56.
2. Robbins J, Sufit R, Rosenbeck J, Levine R, Hyland J. A modification of the modified barium swallow. *Dysphagia* 1987; 2:83-86.
3. Adnerhill I, Ekberg O, Groher M. Determining normal bolus size for thin liquids. *Dysphagia* 1989;4:1-3.
4. Chen M, Ott D, Peele V, Gelfand D. Oropharynx in patients with cerebrovascular disease: evaluation with videofluoroscopy. *Radiology* 1990;176:641-643.
5. Feinberg M, Ekberg O. Videofluoroscopy in elderly patients with aspiration: importance of evaluating both oral and pharyngeal stages of deglutition. *AJR Am J Roentgenol* 1991; 156:293-296.
6. Logemann J. Evaluation and treatment of swallowing disorders. San Diego: College-Hill Press, 1983.
7. Logemann J, Kahrilas P, Kobara M, Vakil N. The benefit of head rotation on pharyngoesophageal dysphagia. *Arch Phys Med Rehabil* 1989;70:767-771.
8. Blitzer A. Approaches to the patients with aspiration and swallowing disabilities. *Dysphagia* 1990;5:129-137.
9. Logemann J. Treatment for aspiration related to dysphagia: an overview. *Dysphagia* 1986;1:34-38.
10. Logemann JA, Kahrilas PJ. Relearning to swallow after stroke—application of maneuvers and indirect biofeedback: a case study. *Neurology* 1990;40:1136-1138.
11. Horner J, Buoyer F, Alberts M, Helms M. Dysphagia following brain-stem stroke: clinical correlates and outcome. *Arch Neurol* 1991;48:1170-1173.
12. Horner J, Massey EW, Riski JE, Lathrop DL, Chase KN. Aspiration following stroke: clinical correlates and outcome. *Neurology* 1988;38:1359-1362.

13. Martens L, Cameron T, Simonsen M. Effects of a multidisciplinary management program on neurologically impaired patients with dysphagia. *Dysphagia* 1990;5:147-151.
14. Kasprisin A, Clumeck H, Nino-Murcia M. The efficacy of rehabilitative management of dysphagia. *Dysphagia* 1989;4:48-52.
15. Groher M. Bolus management and aspiration pneumonia in patients with pseudobulbar dysphagia. *Dysphagia* 1987;1:215-216.
16. DePippo K, Holas M, Reding M. The Burke Dysphagia Screening Test: validation of its use in patients with stroke [abstract]. *Stroke* 1993;24:173.
17. DePippo K, Holas M, Reding M. Validation of the 3 oz. water swallow test for aspiration following stroke. *Arch Neurol* 1992;49:1259-1261.
18. Reding M, Potes E. Rehabilitation outcome following initial unilateral hemispheric stroke: life table analysis approach. *Stroke* 1988;19:1354-1358.
19. Folstein MF, Folstein SE, McHugh P. Mini-mental state: a practical method for grading the cognitive state of patients for the clinician. *J Psychiatr Res* 1975;12:189-198.
20. Mahoney F, Barthel D. Functional evaluation: the Barthel index. *Md Med J* 1965;2:61-65.
21. Holas M, Halvorson K, Reding M. Videofluoroscopic evidence of aspiration and relative risk of pneumonia or death following stroke [abstract]. *Clin Res* 1990;38:796A.
22. Holas M, DePippo K, Reding M. Timing of aspiration and relative risk of death following stroke [abstract]. *Clin Res* 1991;39:664A.



©Reprinted from *NEUROLOGY*, Volume 44, Number 9, September 1994

AN ADVANSTAR  PUBLICATION Printed in U.S.A.