

Survival Estimates for Patients with Abnormal Swallowing Studies

Mark E. Cowen, MD, MSc, Sherry L. Simpson, RN, MSN, Theresa E. Vettese, MD

OBJECTIVE: To better understand the life expectancy of patients who have an abnormal videofluoroscopic swallowing study.

DESIGN: Retrospective cohort study. The common starting point was the time of the severely abnormal swallowing study. Hospital charts were reviewed for clinical variables of potential prognostic significance by reviewers blinded to the outcome of interest, survival time.

SETTING: A university-affiliated, community teaching hospital.

PATIENTS: One hundred forty-nine hospitalized patients who were deemed nonoral feeders based on their swallowing study. Patients excluded were those with head, neck, or esophageal cancer, or those undergoing a thoracotomy procedure.

MEASUREMENTS AND MAIN RESULTS: Clinical and demographic variables and time until death or censoring were measured. Overall 1-year mortality was 62%. Multivariable Cox proportional hazards analyses identified four variables that independently predicted death: advanced age, reduced serum albumin concentration, disorientation to person, and higher Charlson comorbidity score. Eighty patients (54%) subsequently underwent placement of a percutaneous endoscopic gastrostomy (PEG) tube after their swallowing study.

CONCLUSIONS: Mortality is high in patients with severely abnormal swallowing studies. Common clinical variables can be used to identify groups of patients with particularly poor prognoses. This information may help guide discussions regarding possible PEG placement.

KEY WORDS: videofluoroscopic swallowing study; percutaneous endoscopic gastrostomy (PEG); nonoral feeding; survival. *J GEN INTERN MED* 1997;12:88-94.

When patients cannot meet their nutritional needs by mouth or are at high risk of aspirating food, tube feedings may be required.¹ A videofluoroscopic swallowing study (VFSS) is often ordered to determine the risk of aspiration, and the underlying physiologic and anatomic reasons for the swallowing dysfunction.²⁻⁴ The prevalence of some swallowing difficulty in inpatients is at least 12%,⁵ and is in the 20% to 40% range for patients with

strokes,⁶⁻⁸ dementia,^{9,10} or other neurologic conditions.^{11,12} Traditionally the most common method of tube feeding was via a nasogastric tube. Since 1980, the percutaneous endoscopic gastrostomy (PEG) method has become popular for long-term tube feedings because it is reasonably safe and comfortable for the patient.¹³

The decision to place a PEG tube is not always straightforward. A recent survey of nursing home residents found only 33% would choose tube feedings if they were no longer able to eat.¹⁴ Some clinicians also feel PEG tube placement may be inappropriate for patients who are expected to die soon.^{13,15-17} Many advanced directives or living wills have options for patients to refuse life-sustaining treatments if they have a terminal illness, or if the "burdens of the treatment outweigh the expected benefits."^{18,19} Conversely, if a patient wanted to live longer or allow time for the medical conditions to improve, then prolongation of life could be considered a benefit,^{20,21} and tube feedings justifiable.

The first step in the decision-making process is to estimate the expected survival of a patient who has abnormal swallowing, then estimate the potential benefit of PEG placement. The medical literature currently provides only part of the necessary information. Of stroke patients with swallowing difficulties, 45% to 68% are dead within 6 months.^{6,22,23} A recent study reported a survival advantage for stroke patients randomized to feedings by the PEG route versus nasogastric route.²⁴ How such patients would fare without any form of tube feedings is not known. Still less is known for nonstroke conditions. Most investigators study patients after the PEG tube has been placed. As shown in Table 1, the mortality rate for these patients is high: 2% to 27% are dead within 30 days, and approximately 50% or more within 1 year.^{16,25-40} Although informative, these studies cannot provide survival estimates for those who might not choose PEG feedings.

Such information could be obtained from a randomized, controlled trial of patients having and not having PEG tubes, with a sample size sufficient to allow identification of prognostic factors. Yet, to conduct such a study would require the participants (and their families) to be sufficiently neutral toward tube feedings to allow randomization in the first place. At this point in time, enrolling such patients in the United States would be difficult. However, some insights might be achieved through a retrospective cohort analysis, starting at the time of an abnormal swallowing study, whether or not a PEG was subsequently placed. We therefore undertook the following study to examine life expectancy in these patients, and to begin identifying important prognostic factors in those eligible to receive tube feedings.

Received from St. Joseph Mercy Hospital, Ann Arbor, Mich. (MEC, SLS, TEV), and Department of Medicine, University of Michigan Medical School, Ann Arbor (MEC).

Address correspondence and reprint requests to Dr. Cowen: St. Joseph Mercy Hospital, P.O. Box 992, Ann Arbor, MI 48106.

Table 1. Published Studies on PEG Tubes with More Than 50 Patients*

Study	Treatment	Number of Subjects	Mortality, %				Mortality Risk Factors
			30 Day	60 Day	6 Month	1 Year	
Rabeneck et al. ²⁵	PEG	7,369				59	Age
Miller et al. ²⁶	PEG	316	17				Not reported
Larson et al. ²⁷	PEG	314	16				Not reported
Horton et al. ²⁸	PEG	224	8				Not reported
Wolfsen et al. ²⁹	PEG	191	21	33	50		Not reported
Raha and Woodhouse ³⁰	PEG	179	20				Placed for supplemental nutrition
Stiegmann et al. ³¹	PEG, OG	131	2				Not reported
Stuart et al. ³²	PEG, OG	125	27				Pulmonary cachexia, malignancy
Zabel et al. ³³	PEG, PEGJ, PEJ	118	18		46		Aspiration history, acute neurologic
Taylor et al. ¹⁶	PEG	97	22			50	Age, male, diabetes
Fay et al. ³⁴	PEG	80	16	50			Not reported
	NG	29	28	50			Not reported
Llaneza et al. ³⁵	PEG	73	26				Not reported
Slezak and Kofol ³⁶	PEG	71	13				Not reported
Ciocon et al. ³⁷	PEG, NG	70	5			50	Aspiration history
Jarnagin et al. ³⁸	PEG	64	17				Aspiration history
Gay et al. ³⁹	PEG	58		50 [†]			Not reported
Samii and Suguitan ⁴⁰	PEG	51	10				Not reported

*PEG indicates percutaneous endoscopic gastrostomy; PEJ, jejunostomy; PEGJ, peg-jejunal tubes; OG, operative gastrostomy; NG, nasogastric tube.

[†]90-day mortality.

METHODS

Study Site

St. Joseph Mercy Hospital (Ann Arbor, Mich.) is a 560-bed, university-affiliated, community teaching hospital. Because swallowing studies could be coded differently on billing data, we obtained lists for all inpatients who had either a barium swallow study or VFSS during years 1990–1992. This study focused on inpatients, to allow more efficient data collection. Of 1,056 patient records requested, 1,010 were able to be retrieved and reviewed.

Study Exclusion Criteria

Of the 1,010 charts reviewed, 122 of the patients had a barium swallow examination only and so were excluded, leaving 888 patients who had had a VFSS. Of these, 739 patients were not included in the study cohort for the following reasons: they were allowed to eat (usually a modified diet) based on the VFSS results, and so were not candidates for tube feedings ($n = 577/888$ or 65% of VFSS patients); or they already had a PEG tube placed at the time of the VFSS ($n = 79$, 9%). Patients were also excluded if they had a thoracotomy on the same hospital admission (for example, coronary artery bypass, $n = 33$, 4%), because patient variables changed frequently during the postopera-

tive period and PEG placement could be considered part of the postoperative care. Other exclusions were patients for whom the decision to place a PEG tube seemed more straightforward: those with oropharyngeal carcinoma, carcinoma of the thyroid, esophageal cancer, previous radiation therapy to the neck area, or resection of the epiglottis ($n = 27$, 3%); who had mechanical obstruction from cricopharyngeal spasm ($n = 6$, 1%); who were intubated or had a cuffed tracheostomy ($n = 7$, 1%); were uncooperative ($n = 8$, 1%); or had an esophagectomy or gastrectomy ($n = 2$, 0.2%).

Inclusion Criteria

One hundred forty-nine patients fulfilled the criteria of nonoral feeders despite compensatory strategies. These were patients who were able to participate in the VFSS evaluation for at least one bolus presentation, and had at least one of the following: inability to sustain arousal for 30 minutes several times per day, combined with neurologic deficits or severe deconditioning; inability to propel more than 25% of the bolus to the pharynx; aspiration of more than 1 consistency, or frank, gross aspiration of 1 consistency, with suboptimal alertness; or moderate-to-severe (greater than 50% of the bolus) stasis in the pharynx that could not be cleared with dry swallows or thin liquids.

Outcome

Charts were reviewed by one of four reviewers (three physicians and a nurse) who were blinded to the primary outcome of interest—survival time. All deaths were assumed to have occurred within Michigan owing to the nature of the hospital admitting patterns. Indices compiled from death certificates from the Michigan Department of Public Health were reviewed for years 1990–1993 to determine the date and reported principal cause of death. Patients not known to have died, either by death index or by hospital chart, were assumed to be alive as of the last day of the 1993 index, December 31. One year of follow-up was therefore available for all subjects.

Predictors

Data were collected on a number of variables as of the date of the VFSS: patient demographics, level of alertness (normal/impaired), skin decubiti (yes/no), urinary incontinence or catheterization (yes/no), and coexisting comorbidities (counted if currently present or if there was a history of the condition).⁴¹ Serum albumin concentration (g/dl) was also recorded on the day of the VFSS, if available. If a level was not available, then the level for the most recent prestudy date was used, or if that was not available, then the first reported level after the study was used. If no serum albumin value could be found (for 18/149 patients), we imputed the mean value of the entire study group. The best level of orientation (person, place, and time) achieved prestudy was also recorded, resulting in a binary variable for being at least oriented to person or not. For 19 of the 149 patients, the level of orientation was indeterminate or missing. In these cases, we chose to err on the side of biasing in favor of the null hypothesis, meaning these patients were assumed to be oriented to person.

The hospital course following the VFSS was reviewed to determine whether or not a PEG tube was placed before hospital discharge. If a PEG was not placed, the reason was listed. This resulted in three categories of patients post-VFSS: PEG tube placed ($n = 80$), PEG tube not placed because of rapid clinical improvement prior to hospital discharge (“improved” group, $n = 18$), and PEG tube not placed due to comfort considerations ($n = 51$). This latter category included patients who refused (or whose families refused) any form of tube feedings ($n = 28$), patients discharged with some form of tube feeding by the nasogastric route ($n = 10$), patients who died before receiving a PEG ($n = 12$), and one patient who was transferred to another hospital.

Statistical Analysis

All analyses were performed using the SAS software package (SAS Institute, Cary, NC). Overall group survival was estimated with a Kaplan-Meier curve. Univariate predictors of mortality risk were identified by the log-rank test

for categorical variables, and by single-variable Cox proportional hazards regressions for continuous variables. Multivariable Cox proportional hazards models were constructed from candidate variables related to survival with values of $p = .20$ or less on univariate analyses. The final multivariable model was determined using backwards elimination, with the criterion for retention set $p = .05$. In order to detect overfitting that might occur from multiple significance testing with the backwards elimination procedure, the coefficients and standard errors were reevaluated using the bootstrap technique. This involved selecting 1,000 bootstrap samples, each containing 149 “subjects” selected with replacement from our data set. A separate proportional hazards model was developed from each sample, and the mean and standard deviations from the 1,000 sets of regression coefficients were calculated. As the mean regression coefficient and the corresponding standard deviation provide a more valid (less prone to overfitting) reflection of the magnitude and the precision of the effect of each factor in the final model, a comparison of these values with the coefficients and standard errors of the final model provides a mechanism for assessing the validity of that model. Finally, graphs displaying survival patterns for various combinations of the prognostic variables were constructed.

RESULTS

The characteristics of the study population are presented in Tables 2 and 3. The mean age was 76.2 years, 41.6% were women, and 89.9% were white. Most of the patients had serious comorbid conditions, with a mean Charlson score of 3.48. The most frequent conditions were cerebrovascular accident (56.4%), hemiplegia (41.6%), congestive heart failure (32.2%), and dementia (20.1%).

Overall Group Analysis

The median survival of the study population was 159 days (95% confidence interval [CI] 72, 276 days), estimated 30-day mortality was 27%, 90-day mortality 42%, and 1-year mortality 62%. Causes of death as recorded on the death certificates were cardiac (29.8%), cerebrovascular (18.3%), cancer (10.6%), other neurologic conditions (6.7%), diabetes (5.8%), pneumonia (5.8%), chronic obstructive lung (5.8%), and other (17.3%).

Table 3 summarizes the univariate analyses. The mortality rate ratio (RR), or risk of death, was increased in those with advancing age, lower serum albumin concentration, higher Charlson comorbidity category, and in those who had had a myocardial infarction, congestive heart failure, cerebrovascular disease, or lymphoma. Patients disoriented to person were at borderline increased risk (RR 1.73; 95% CI 0.90, 3.33).

The multivariable proportional hazards model identified four variables that were independently associated with an increased likelihood of death: advanced age cate-

Table 2. Characteristics of Study Population

Characteristics	Number
Gender	
Female	62 (41.6 %)
Male	87 (58.4 %)
Race	
White	134 (89.9 %)
Nonwhite	15 (10.1 %)
Alert, yes	104 (69.8 %)
Urinary incontinence	126 (84.6 %)
Skin decubiti	30 (20.1 %)
Mean age, years	76.2 (SD 12.3)
Mean serum albumin, g/dl	2.99 (SD 0.51)
Mean Charlson comorbidity score	3.48 (SD 2.48)

gory (RR 1.48 compared with the next younger category, 95% CI 1.10, 2.00), reduced serum albumin category (RR 1.29 compared with the next higher category, 95% CI 1.04, 1.59), disorientation to person (RR 2.29 over those who were oriented, 95% CI 1.16, 4.53), and higher Charlson comorbidity category (RR 1.82 compared with the next lower category, 95% CI 1.39, 2.37). These remained significant predictors when reevaluated by the bootstrap technique. Figure 1 displays projected survival patterns based on various combinations of the explanatory variables in the multivariable model. As shown, most combinations of the risk factors projected median survivals of less than 6 months.

Subgroup Analysis

Survival curves for the three categories of patients based on subsequent PEG tube status (PEG, comfort care, and improved) are shown in Figure 2 ($p = .0001$). Unadjusted median survival was 33 days for the comfort group (95% CI 9, 124 days), and 181 days for the PEG group (95% CI 70, 318 days). Patients in the improved group had their clinical improvement, on the average, within 13.8 days after their VFSS. These patients were younger, more likely to be men, and had higher serum albumin concentrations than the other subgroups. The survival advantage of the improved and the PEG groups compared with the comfort care group remained after adjusting for the four survival determinants in the multivariable model (improved RR 0.09, 95% CI 0.03, 0.31; PEG RR 0.48, 95% CI 0.32, 0.74).

DISCUSSION

The focus of this study was to derive survival estimates for patients with abnormal swallowing studies, in order to help clinicians and patients with the tube feeding decision. Our study group was composed of 17% of all patients who had had a VFSS in our hospital. This is near the midpoint for the reported prevalence of 12% to 32% for severe dysfunction as demonstrated by VFSS.^{8-11,42} We found these patients to be at high risk of dying in the ensuing year. At particular risk were patients with advanced age, increasing comorbidity, low serum albumin concen-

Table 3. Univariate Mortality Risk Factors

Categorical Variable	Number of Patients (%)	Relative Hazard (Confidence Interval)	30-Day Mortality, (%)	180-Day Mortality, (%)
Age, years		1.64* (1.25, 2.14)		
>80	62 (41.6)		35.5	64.5
70-79	56 (37.6)		23.2	50
<70	31 (20.8)		12.9	32.3
Albumin, g/dl		1.30* (1.07, 1.56)		
<2.5	22 (14.8)		27.3	59.1
2.5-2.99	42 (28.2)		23.8	54.8
3.00-3.49	60 (40.3)		33.3	58.3
3.5-3.99	19 (12.8)		15.8	36.8
>4.0	6 (4)		0	0
Charlson score		1.62* (1.25, 2.08)		
≥6	21 (14.1)		42.9	71.4
4-5	44 (29.5)		23.1	61.4
≤3	84 (56.4)		16.7	42.9
Myocardial infarction	29 (19.5)	1.64 (1.04, 2.59)	34.5	69
Congestive heart failure	48 (32.2)	1.82 (1.22, 2.7)	39.6	64.6
Cerebrovascular disease	84 (56.4)	1.5 (1.01, 2.22)	31	56
Lymphoma	1 (0.7)	24.33 (2.93, 202.1)	100	100
Not oriented to person	11 (7.4)	1.73 (0.90, 3.33)	18.2	72.7

*Risk compared with next level.

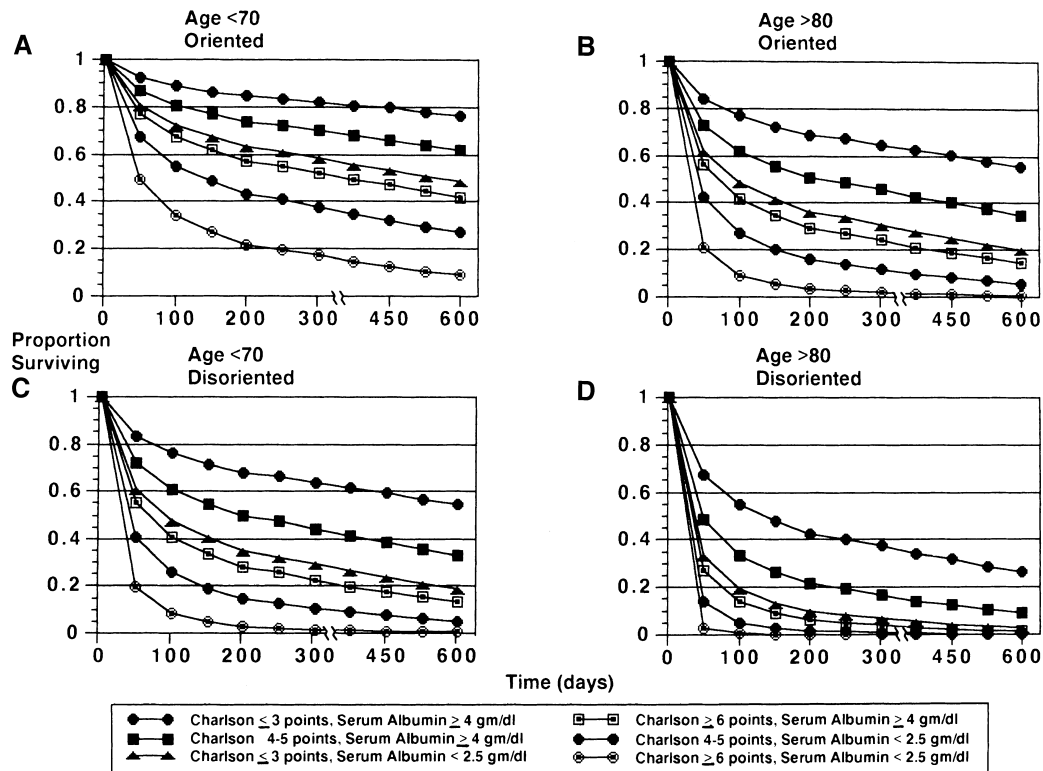


FIGURE 1. Projected survival estimates based on the multivariable model. For all panels, curves represent combinations of Charlson comorbidity scores and serum albumin levels (g/dl): (A) age less than 70, and oriented to person; (B) age greater than 80, and oriented to person; (C) age less than 70, and disoriented to person; (D) age greater than 80, and disoriented to person.

tration, and disorientation to person. After adjusting for these predictors, patients with PEG tubes placed after their VFSS survived twice as long as those in the comfort care group. A subset of patients, comprising 12% of the study cohort, avoided a PEG tube because of their rapid clinical improvement, occurring on average within 2 weeks of the swallowing study.

Mortality rates and previously identified predictors of death in patients with PEG tubes are shown in Table 1. In our study, we were able to confirm the increased risk associated with advancing age. We were unable to confirm the increased risk associated with male gender and diabetes. The differences in clinical predictors can best be explained by patient selection factors. The other studies began follow-up after patients had been selected for PEG placement for various reasons. Our study began at an earlier time in the clinical course, at the time of an abnormal VFSS, and more closely approximated the point in time when the decision for or against a PEG is made. Other differences in results can be explained by patient inclusion criteria and study settings. For example, we did not include patients with oropharyngeal or esophageal cancer in our study. It is also possible that our study lacked the necessary statistical power to confirm the findings from the other studies.

Despite these differences, the mortality rate is similarly high in these studies and in ours. The 62% one-year mor-

tality of our patients was similar to the 59% rate in patients with Charlson points of 3 or greater.⁴¹ For stroke patients, the 56% six-month mortality in our series was nearly identical to mortality rates found in two other recent studies.^{6,16}

The clinical predictors identified in our study are not novel. Age,⁴³ Charlson score,^{41,43} serum albumin,⁴⁴⁻⁴⁶ and cognitive impairment (our disorientation variable)^{47,48} have all been previously identified as mortality risk factors. In a sense, we have validated these as predictors for the population of patients with severely abnormal VFSS.

This study has a number of important limitations. It was not a randomized clinical trial comparing survival between patients fed via the PEG route, versus no tube feedings. Our control group was a heterogeneous group that included patients who died in the hospital (12/51), those who had tube feedings by a non-PEG route (10/51), and those who refused any form of tube feedings (28/51). It appears that patients who underwent PEG placement survived approximately twice as long as those who did not, after controlling for the four mortality risk factors. It is likely the survival advantage was due to other prognostic factors which were influencing the decision to place the PEG tube. However, these remain unidentified. We therefore cannot prove the benefit of a PEG tube by this study design.

Another potential limitation is with the identification of the mortality risk factors. The choice of comorbidities

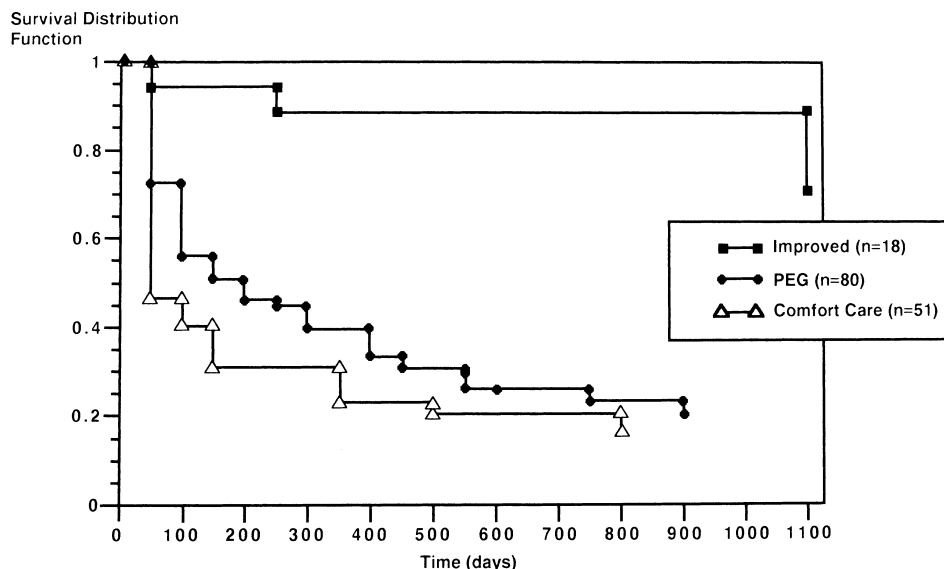


FIGURE 2. Kaplan-Meier curves according to PEG status. Unadjusted survival curves according to PEG status. The top curve represents the clinically improved group; the middle curve, those who underwent PEG placement; the lower curve, those without PEG placement, comfort care status.

was based on the prognostic factors identified by Charlson et al.⁴¹ However, we did not distinguish between active versus historical problems for the patient, nor did we identify levels of illness severity within the conditions. As currently defined, the number of comorbidities appears to have prognostic significance in the population of patients with abnormal swallowing. It is unknown if more precise prognostic information would be gained by further stratifying these based on current level of disease activity. Similarly, the variable for cognitive dysfunction was rather crude—disorientation to person or not. If this could not be determined by chart review, then patients were assigned to the default category, orientation to person. One can hypothesize that more precise information would have improved the explanatory ability of this variable. In this same line of reasoning, the serum albumin variable can be criticized because the test was ordered at different times by different clinicians. Another problem is that missing values were assigned the mean value for the group. These flaws would tend to weaken the inverse relation between the serum albumin level and mortality risk. Because a number of factors may influence the serum albumin level,^{45,46} controlling for the acuity or chronicity of the underlying conditions might further refine this explanatory variable. Many of these discussed limitations are in part due to the retrospective cohort study design. Nevertheless, such a study has merit if it is viewed as an initial step in understanding the prognosis of these patients.

A final limitation is the absence of a “testing” set, a second cohort of patients on which to test the validity of the explanatory variables. We began the validation effort by submitting all of our multivariable regression models to bootstrap testing. This demonstrated that the selected

multivariable parameters remained significant through 1,000 replications, suggesting the stability of our findings. However, before the results could be applied with confidence to an individual patient, more definitive validation must be done.⁴⁹

It is important not to overstate the applicability of our study to individual decision making. At best, it provides a context for patient-physician dialogue. The reported survival estimates are a starting point for estimating the prognosis for patients with severely abnormal swallowing studies, rather than a formal clinical predictive rule. At this time, to extend these estimates for a group to an individual also will require the clinician to consider other prognostic information such as the likelihood of reversibility of the medical conditions,^{20,21,50} disease-specific predictors found in the literature, individual patient characteristics, and clinical judgment.⁴⁵ Quality of life, not addressed in our study, also must be considered.^{20,21,51} The decision for or against tube feedings must be based on all information at hand, imprecise as it might be. Further studies are needed to provide clinicians, patients, and families with clearer guidelines for these difficult decisions.

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