Methods Section

Is Use of Mechanical Ventilation a Reasonable Proxy Indicator for Coma Among Medicare Patients Hospitalized for Acute Stroke?

Ronnie D. Horner, Richard J. Sloane, and Katherine L. Kahn

Objective. To ascertain whether use of mechanical ventilation on admission to the hospital is a proxy indicator of coma (i.e., very severe stroke) among acute stroke patients.

Methods. A secondary analysis of data from a medical record review on a nationally representative sample of 2,824 Medicare patients, ages 65 years or older, who were hospitalized for stroke in 1982–1983 or 1985–1986 in 297 acute care hospitals in 30 areas within five geographically dispersed states.

Results. Use of mechanical ventilation on the first day of hospitalization was significantly associated with level of consciousness on admission: <2 percent of noncomatose patients versus 17.5 percent of comatose ($p < .001$). With a high specificity and high likelihood ratio for a positive test, use of mechanical ventilation on the first day of hospitalization ruled-in coma. It was also significantly associated with severity of illness, prognostic indicators (i.e., admission through the emergency room, admission to intensive care, and having a "do-not-resuscitate" order written during the hospital stay), and with in-hospital death. Adjusting for patient demographics, stroke type, comorbidity, and process of care, early initiation of mechanical ventilation remained significantly associated with both coma and in-hospital death.

Conclusions. A stroke patient's use of mechanical ventilation on the first day of hospitalization is a valid proxy indicator of level of consciousness.

Key Words. Cerebrovascular disorders, critical care, patient outcome assessment, prognosis, artificial respiration

In studies of the diagnosis, treatment, and outcomes of cerebrovascular disease, it is essential to adjust for the severity of each patient's stroke in addition to the type of stroke. Although numerous scales and indexes for measuring stroke severity exist, all require detailed clinical data that describe neurologic status, for example, response to pain, orientation, and motor function (Cote,

Hachinski, Shurvell, et al. 1986; Goldstein, Bertels, and Davis 1989; Mathew, Meyer, Rivera, et al. 1972; Orgogozo 1989; Oxbury, Greenhall, and Grainger 1975; Scandinavian Stroke Study Group 1985). These types of data are rarely, if ever, available in large national, regional, or local administrative databases–such as the National Hospital Discharge Survey and Medicare data from the Health Care Financing Administration–that increasingly are used to conduct preliminary analyses of patterns of care and patient outcomes among stroke patients. Nor do these databases contain variables that are indicative of broad categories of stroke severity; for example, these databases do not routinely record level of consciousness or, more specifically, coma that is prognostic of survival and functional status, ultimate indicators of severe versus mild or moderate stroke (Goldstein and Matchar 1994). Consequently, studies that use data from these types of administrative databases generate results that are not fully informative and that may be invalid.

If analyses of extant data are to be more useful, investigators need to identify a proxy or indirect indicator for stroke severity that is based on a variable or set of variables from among those that are included routinely. An indicator of severe versus mild or moderate stroke is particularly important because patient outcomes and, perhaps, the degree of physician discretion in clinically managing the patient are most likely to show the greatest difference between these two categories of stroke patients. No studies have yet identified an acceptable proxy indicator of this nature.

Among the variables that are typically available in the large databases are diagnoses, and diagnostic and therapeutic procedures. Often times stroke, particularly hemorrhagic stroke and ischemic stroke of the brainstem or one

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Address all correspondence and requests for reprints to Ronnie D. Horner, Ph.D., Senior Health Scientist, HSR&D (152), VA Medical Center, Durham, NC 27705. Dr. Horner is also Associate Research Professor of Medicine, Division of General Internal Medicine, Department of Medicine, Duke University. Richard J. Sloane, M.P.H. is Biostatistician, HSR&D, VA Medical Center, Durham, NC; Katherine L. Kahn, M.D. is Senior Natural Scientist, Health Program, RAND, and Professor of Medicine, Division of General Internal Medicine and Health Service Research, Department of Medicine, UCLA. This article, submitted to *Health Services Research* on June 7, 1996, was revised and accepted for publication on February 3, 1997.

that affects both cerebral hemispheres, impairs the patient's consciousness (Goldstein and Matchar 1994; Barnett et al. 1992). Moreover, cerebral edema, one of the more common complications of severe stroke, often occurs early after ictus and may result in respiratory abnormalities, necessitating mechanical ventilation either on admission or shortly thereafter (Grotta, Pasteur, Khwaja, et al. 1995). Thus, if initiated early in the hospitalization, use of mechanical ventilation may be a reasonable indicator of coma and, hence, of very severe stroke. In this report, we present evidence regarding the validity of using 'mechanical ventilation on the first hospital day' as a proxy indicator of coma at the time of hospital admission.

METHODS

STUDY POPULATION

This is a secondary analysis of data from a national study of the quality of hospital care provided to a representative sample of Medicare patients during two time periods: 1981–1982 and 1985–1986. (Draper, Kahn, Reinisch, et al. 1990; Kahn, Keeler, Sherwood, et al. 1990; Kahn, Draper, Keeler, et al. 1992; Kahn, Rubenstein, Draper, et al. 1990; Kahn, Pearson, Harrison, et al. 1994; Kahn, Rogers, Rubenstein, et al. 1990; Keeler, Kahn, Draper, et al. 1990; Kosecoff, Kahn, Rogers, et al. 1990; Rogers, Draper, Kahn, et al. 1990; Rubenstein, Kahn, Reinisch, et al. 1990). The study cohort comprises the 2,824 patients who were hospitalized for stroke at any of 297 hospitals located in 30 communities within five geographically dispersed states. Administrative and clinical data, obtained by medical record review, included patient demographics, health insurance, neurologic signs and symptoms at time of admission, process of care, use of selected inpatient services, status at discharge, and discharge destination. Interrater reliability of the abstracted data was high with the average item kappa being 0.78; the 90th percentile for item kappas was 1.0 and the 10th percentile was 0.63 (Draper, Kahn, Reinisch, et al. 1990). For data elements specific to cerebrovascular disease, interrater reliability was similarly high with no kappa below 0.62; for example, presence of cerebrovascular accident signs and symptoms showed no variability across raters and "presence of coma" had a kappa of 0.64 (Kahn, Draper, Keeler, et al. 1992).

USE OF MECHANICAL VENTILATION

Our proxy indicator for coma (i.e., level of consciousness on admission) was defined as the initiation of mechanical ventilation on the first day of the

hospital stay (1 = mechanical ventilation begun on the first day of hospitalization; 0 = otherwise).

STROKE SEVERITY

Our primary measure of stroke severity was neurologic status on admission as indicated by level of consciousness. Level of consciousness was determined from physicians' notes in the medical record that described, for the initial 24-hour period of hospitalization, the patient's orientation to surroundings and awareness of pain. Patients were classified into one of four categories: alert, confused, lethargic/stuporous, or comatose. For the few patients for whom more than one level of consciousness was noted, the more impaired level of consciousness was used. If no impairment of consciousness was indicated, the patient was classified as alert. Level of consciousness was ultimately dichotomized as comatose versus noncomatose to reflect severe stroke versus mild or moderate stroke.

As an alternative measure of neurologic status, we used number of types (or categories) of stroke-related deficits on admission. Five types of deficits were derived from physician-written notes relating to the neurologic evaluation; these included facial, motor, sensory, speech, and visual deficits. Because the severity of each deficit was not recorded, this characteristic of the deficit could not be incorporated into the definition of the variable corresponding to the deficit. Therefore, a discrete variable was created that indicated the total number of types of deficits the patient had at the time of presentation.

As secondary measures of stroke severity we used several variables that were either correlated with the patient's severity of illness on admission or were prognostic indicators. One measure was whether the patient had been admitted to the hospital through the emergency room (1 = yes, 0 = no). Another was whether the patient had been admitted to the intensive care unit at any time during the stay (1 = yes, 0 = no). A third measure was do-not-(attempt)-resuscitation (DNR) orders having been written in the medical record during the patient's hospital stay (1 = yes, 0 = no). Fourth, we used the RAND sickness-at-admission scale that reflects the patient's short-term prognosis; a higher score indicates a higher probability of death. The composition, validity, and reliability of the RAND sickness-at-admission scale has been described elsewhere (Keeler, Kahn, Draper, et al. 1990).

PATIENT OUTCOMES

For our outcome measures, we used in-hospital death and length of stay. For

length of stay, we examined the overall length of stay and length of stay stratified by discharge status (i.e., alive or deceased).

DATA ANALYSIS

The patient was the unit of analysis. The primary analysis involved bivariate comparisons of each measure of severe stroke with the use of mechanical ventilation. The statistical significance of these associations was assessed by the chi-square statistic for categorical variables and the *t*-test or its nonparametric equivalent for continuous variables.

With level of consciousness on admission (i.e., coma versus all other levels) as our "standard," we ascertained the "diagnostic" performance of early mechanical ventilation through the following indexes: sensitivity, specificity, positive and negative predictive values, likelihood ratio for a positive and negative test, and the receiver operating characteristics (ROC) curve. These indexes were calculated according to standard formulas (Fleiss 1981; Sackett et al. 1992).

We also used multiple logistic regression to assess the association between use of mechanical ventilation and level of consciousness (comatose versus all other levels) adjusting for patient demographics, type of stroke (hemorrhagic versus ischemic), and a set of factors that may be associated with the use of mechanical ventilation independent of the stroke, such as the patient's physical health status and the quality of care received. This set of factors included comorbidity, issuance of DNR orders, admission from a nursing home, and an index of quality of care. Comorbidity was measured by a set of dichotomous variables indicating the presence of conditions that complicate the clinical management of stroke patients and may adversely affect their outcome, atrial fibrillation or other cardiac arrhythmias, chronic obstructive pulmonary disease, congestive heart failure, diabetes mellitus, hypertension, and prior myocardial infarction. Dichotomous variables were also used to indicate whether the patient (1) had a DNR order written at any time during the hospitalization, and (2) was admitted from a nursing home.

Quality of care was measured by the RAND process of care score, a valid and reliable index that explicitly measures one aspect of the quality of care provided to hospitalized patients (Kahn, Rogers, Rubenstein, et al. 1990). The RAND process of care index is based on (1) several key indicators of the assessment of the patient's initial status by physicians and nurses, (2) diagnostic testing, (3) therapies employed, and (4) ongoing monitoring of the patient's

status. For stroke, these key process indicators were whether a physician or nurse had obtained information on prior cerebrovascular accident(s), tested the patient's gag reflex, obtained three or more blood pressure readings, obtained an echocardiogram, and obtained a serum potassium level, all within two days of the patient's admission to the hospital.

Although the patient cohort was derived by complex sampling, the presented data were neither weighted nor adjusted for design effects, because previous findings based on the full data set indicated that weighted and unweighted analyses yielded similar results and that design effects were minimal (Kahn, Pearson, Harrison, et al. 1994).

RESULTS

CHARACTERISTICS OF THE PATIENT COHORT

Approximately 4 percent of stroke patients ($n = 119$) received mechanical ventilation on the first day of hospitalization; an additional 25 patients in the cohort began mechanical ventilation on the second day of hospitalization or later. When patients who did and did not receive mechanical ventilation on their first day in the hospital were compared on characteristics that may influence the approach to clinical management or patient outcomes, clear differences were found only among clinical characteristics (Table 1). The largest difference occurred for type of stroke with a larger proportion of patients who began mechanical ventilation on their first hospital day having had a hemorrhagic stroke, a generally more severe type of stroke than ischemic stroke. A smaller proportion of the mechanically ventilated patients also had been ambulatory prior to admission, suggesting that these patients may have had more compromised physical health status prior to their stroke.

For patient demographics and the characteristics of the admitting hospital, few significant differences were found between stroke patients who were and were not mechanically ventilated on the first day of their admission (Table 1). A significantly larger proportion of the mechanically ventilated patients were hospitalized at large, urban teaching facilities. Based on the RAND process of care score, they also received a higher quality of care relative to patients who did not receive mechanical ventilation on the first day of hospitalization.

LEVEL OF CONSCIOUSNESS AND USE OF MECHANICAL VENTILATION

There was an inverse association between the percentage of patients receiving

mechanical ventilation on the first day of hospitalization and level of consciousness on admission (Table 2). A substantial difference existed in the proportion of comatose versus noncomatose patients who received mechanical ventilation, with patients who were comatose on admission being at least 13-fold more likely to receive mechanical ventilation on their first hospital day than patients who were not in a coma. Of the 119 patients who received mechanical ventilation on their first day in the hospital, 111 (93.3 percent) were in coma.

As a proxy indicator of coma among stroke patients, the use of mechanical ventilation on the first day of hospitalization had a very high specificity but low sensitivity (Table 3). Given the high specificity, a positive test (i.e., use of mechanical ventilation) was strongly indicative of coma in stroke patients, ruling-in coma. Consistent with this conclusion, the likelihood ratio for a positive test was high (Table 3). With pre-test odds of 29 percent of being comatose on admission among these stroke patients, a positive test yielded post-test odds of 93 percent, a substantial improvement in identifying stroke patients who were in coma. A negative test result (i.e., no use of mechanical ventilation on the first day of hospitalization) had little utility in identifying those stroke patients who were comatose on admission. Figure 1 presents the ROC curve associated with use of mechanical ventilation on the first day of hospitalization as an indicator of coma.

The association between the number of stroke-related deficits and the early use of mechanical ventilation was not statistically significant among noncomatose patients (i.e., patients for whom the full range of deficits can be assessed). However, the proportion of these patients having four or more types of stroke-related deficits was twofold greater among those who were mechanically ventilated than among those who did not receive mechanical ventilation during the first day of hospitalization (50.0 percent versus 24.2 percent; $p = .17$). The lack of statistical significance is likely a consequence of the small number of noncomatose, mechanically ventilated patients ($n = 8$). Significantly fewer patients who received mechanical ventilation beginning on the first day of admission as compared to other types of patients subsequently used inpatient physical or occupational therapy (19.4 percent versus 59.2 percent, respectively; $p < .001$).

Among the various secondary measures of the patient's severity of illness at the time of presentation, all of the measures indicated clearly and with statistical significance that patients who received mechanical ventilation on the first day of hospitalization were more severely ill (Table 4). Although a high percentage of all stroke patients in this representative sample of Medicare

Table 1: Characteristics of a Representative Sample of 2,824 Medicare Patients Age 65 Years or Older, Who Were Hospitalized for Stroke in 1982–1983 or 1985–1986 According to Use of Mechanical Ventilation on First Day of Hospitalization

	Mechanically Ventilated on Hospital Day 1:		
Characteristic	*Yes (n = 119)*	*No (n = 2,705)*	p-*Value*
Sociodemographic (%)			
Age (in years)			
Mean (± std. dev.)	77.60 (± 7.80)	78.40 (± 7.70)	.260
Median	76.80	77.90	.240
Female gender	63.90	55.20	.060
Have Medicaid	17.70	15.40	.500
Lived alone at home	13.50	17.40	.270
Admitted from nursing home	11.80	11.40	.900
Disease (%)			
Stroke type			
Hemorrhagic	47.90	9.00	<.001
Lacunae	1.70	5.80	.060
Other ischemic	50.40	85.20	<.001
Prior stroke	27.70	35.10	.019
Able to walk before admission	63.00	77.30	.001
Comorbid Conditions (%)			
Atrial fibrillation	14.30	12.50	.560
Chronic obstructive pulmonary disease	14.30	11.70	.390
Congestive heart failure	21.90	16.40	.120
Diabetes mellitus	26.10	23.70	.560
Hypertension	48.70	52.40	.430
Prior myocardial infarction	12.90	15.10	.470
Process of Care			
Process of care score			
Mean (± std. dev.)	0.80 (± 0.87)	−0.03 (± 0.98)	<.001
Median	1.02	0.10	<.001
Admitted Post-PPS (i.e., 1985–1986)	57.10	50.90	.180
Hospital (%)			
Geographic location			
State A	10.10	20.70	.005
State B	21.10	19.70	.730
State C	19.30	19.60	.930
State D	32.80	19.90	.001
State E	16.80	20.00	.390
Hospital ownership			
For-profit	10.90	12.10	.700
Government (i.e., county, state, or federal)	26.10	26.70	.870
Other (e.g., church-affiliated, voluntary)	63.00	61.20	.690

Continued

Table 1: Continued

Characteristic	*Mechanically Ventilated on Hospital Day 1: Yes (n = 119)*	*No (n = 2,705)*	p-*Value*
Bed size			
<= 100	10.90	19.50	.020
101–200	19.30	21.60	.560
201–400	25.20	30.70	.200
401+	44.50	28.20	.001
Urban teaching hospital	16.80	9.80	.012
Urban nonteaching hospital	72.30	75.00	.510
Rural hospital	10.90	15.30	.190

Table 2: Association Between Severity of the Stroke on Admission and Use of Mechanical Ventilation on the First Day of Hospitalization Among a Representative Sample of 2,824 Medicare Patients Ages 65 Years or Older, Who Were Hospitalized for Stroke in 1982–1983 or 1985–1986

*Level of Consciousness on Admission**	n	*Mechanically Ventilated on Hospital Day 1 (%)*
Alert	1187	0.1
Confused	445	0.0
Lethargic/Stuporous	551	1.3
Comatose	641	17.5

* Level of consciousness determined by data in the physician's notes.

patients had been admitted through the emergency room, the proportion of mechanically ventilated patients who were admitted through the emergency room was approximately 40 percent greater than the proportion of patients who did not use mechanical ventilation on the first day of hospitalization. Moreover, the proportion of patients admitted to medical intensive care was three times greater among patients who received mechanical ventilation during the first day of their hospital stay as compared to other patients. Similarly, the proportion of patients who had a DNR order issued during their hospital stay was three and one-half times greater among those patients who were mechanically ventilated on their first hospital day as compared to other patients. Also, the mean and median RAND sickness-at-admission score for patients who began mechanical ventilation on their first hospital day was

Table 3: Performance Characteristics of "Use of Mechanical Ventilation on the First Day of Hospitalization" as an Indicator of the Level of Consciousness on Admission Among a Representative Sample of 2,824 Medicare Patients, Age 65 Years or Older, Who Were Hospitalized for Stroke in 1982–1983 or 1985–1986

	*Levels of Consciousness on Admission**	
Mechanically Ventilation	*Comatose*	*Otherwise*
On hospital day 1	111	8
Otherwise	530	2175

Sensitivity: 111 / (111 + 530) = 17.3%
Specificity: 2175 / (2175 + 8) = 99.6%

Positive predictive value: 111 / (111 + 8) = 93.3%
Negative predictive value: 2175 / (2175 + 530) = 80.4%

Likelihood ratio, positive test: Sensitivity / (1 − Specificity) = 46.8
Likelihood ratio, negative test: (1 − Sensitivity) / Specificity = 0.83

*Level of consciousness determined from data in the physician's notes.

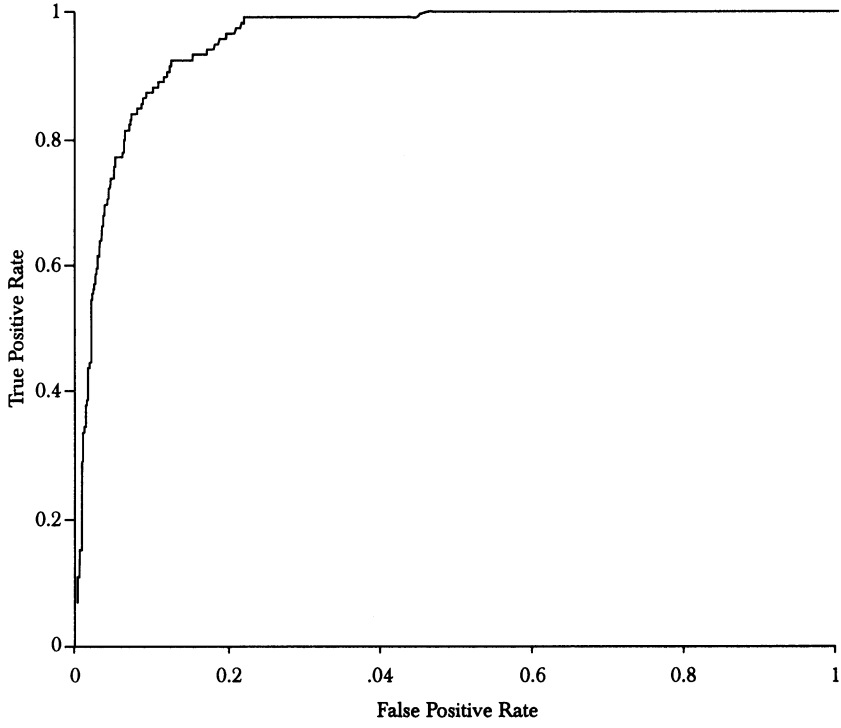
significantly higher than for other patients, indicating a more compromised physical health status generally and a worse prognosis.

With adjustment for concurrent physical health status, process of care, patient demographics, and stroke type, a strong association remained between coma on admission and use of mechanical ventilation on the first day of hospitalization (Table 5). Stroke patients who were comatose on admission were more than 23 times as likely as noncomatose patients to receive mechanical ventilation during the first 24-hours of hospitalization. From the reverse perspective, patients who began mechanical ventilation on the first day of hospitalization were almost 24-times as likely to be comatose on admission than other patients after adjusting for physical health status and process of care (adjusted relative odds = 23.9, 95 percent confidence limits = 11.1, 51.4; $p < .001$).

PROGNOSIS AND USE OF MECHANICAL VENTILATION

As shown in Table 4, the proportion of patients who died in-hospital was four and one-half times greater among patients who were mechanically ventilated on their first day in the hospital as compared to other patients (80.7 percent versus 17.5 percent). Among patients who were subsequently discharged

Figure 1: Receiver Operating Characteristics (ROC) Curve for "Use of Mechanical Ventilation on First Day of Hospitalization" as an Indicator of Coma Among a Representative Sample of 2,824 Medicare Patients, Aged 65 Years or Older, Who Were Hospitalized for Stroke in 1982–1983 or 1985–1986



alive, the mean and median length of stay of the mechanically ventilated patients were longer; however, among those patients who died in-hospital, the mean and median length of stay were shorter for the mechanically ventilated patients. These patterns suggest that patients who began mechanical ventilation on the first hospital day had a more severe stroke than other patients.

With adjustment for patient demographics, stroke type, concurrent physical health status, and process of care, patients who received mechanical ventilation on the first day of hospitalization were approximately eight times more likely to die in-hospital than other patients (adjusted relative odds = 8.2, 95 percent confidence limits = 4.7, 14.3; $p < .001$). For comparison, among

Table 4: Association Between Various Indicators of Severity of Illness and Prognosis, and Use of Mechanical Ventilation on the First Day of Hospitalization Among a Representative Sample of 2,824 Medicare Patients, Age 65 Years or Older, Who Were Hospitalized for Stroke in 1982–1983 or 1985–1986

	Mechanically Ventilated on Hospital Day 1		
Indicator	*Yes (n = 119)*	*No (n = 2680)*	p-Value
Severity of Illness			
Admitted via emergency room (%)	98.30	71.20	<.001
Admitted to intensive care unit during hospital stay (%)	83.20	27.80	<.001
DNR order issued during hospital stay (%)	66.40	19.30	<.001
RAND Sickness on admission score			
Mean (± std. dev.)	0.79 (± 0.17)	0.19 (± 0.20)	<.001
Median	0.83	0.10	<.001
Prognosis			
In-hospital death (%)	80.70	17.50	<.001
Length of stay (in days)			
Overall			
Mean (± std. dev.)	10.1 (± 12.3)	13.7 (± 12.6)	.002
Median	5.0	10.0	<.001
Patients discharged alive	(*n* = 23)	(*n* = 2,233)	
Mean (± std. dev.)	19.1 (± 15.0)	14.3 (± 12.2)	.060
Median	15.0	11.0	.090
Patients discharged dead	(*n* = 96)	(*n* = 472)	
Mean (± std. dev.)	8.0 (± 10.6)	11.2 (± 14.2)	.013
Median	5.0	7.0	.002

stroke patients who were comatose on admission versus patients who were not comatose on admission, the adjusted relative odds of dying in the hospital were 4.1 (95 percent confidence limits = 3.2, 5.3; $p < .001$). (The full set of these logistic regression results are available from the authors on request.)

DISCUSSION

Extant national, regional, and local databases on hospital discharges are a potential resource for conducting preliminary analyses of the patterns of care and outcomes of stroke patients. However, in such studies it is essential to adjust for both stroke type and stroke severity. Stroke type can be accounted for, if only approximately, by the broad categories of hemorrhagic and ischemic stroke as defined by discharge diagnoses. Adjustment for stroke

Table 5: Adjusted Relative Odds of Mechanical Ventilation on the First Day of Hospitalization Associated with Various Characteristics of Stroke Patients, Multivariable Logistic Regression Based on the Experience of a Representative Sample of 2,824 Medicare Patients, Age 65 Years or Older, Who Were Hospitalized for Stroke in 1982–1983 or 1985–1986.

	Mechanically Ventilated on Hospital Day 1:		
Characteristic	*Relative Odds*	*95% CL**	p-*Value*
Stroke Severity (referent = alert, confused, or lethargic)			
Comatose on admission	23.5	10.8, 50.9	<.001
Patient Demographics			
Aged 85 years or older	0.8	0.5, 1.5	.490
Black race	0.6	0.2, 1.4	.240
Female gender	1.3	0.8, 2.1	.320
Comorbidity			
Atrial fibrillation	0.8	0.4, 1.5	.430
COPD	1.1	0.6, 2.1	.790
CHF	1.2	0.7, 2.2	.500
Diabetes mellitus	1.2	0.7, 2.0	.530
Hypertension	0.8	0.5, 1.3	.310
Prior cerebrovascular accident	0.7	0.4, 4.2	.220
Prior myocardial infarction	1.3	0.7, 2.6	.380
Stroke Type (referent = other ischemic)			
Hemorrhagic	3.7	2.2, 6.1	<.001
Lacunae	1.1	0.2, 5.7	.910
Process (quality) of Care			
RAND process score	2.6	1.9, 3.4	<.001
Other Factors			
Admitted to intensive care	3.8	2.2, 6.6	<.001
DNR orders present	2.1	1.3, 3.4	.003
Nursing home resident	0.7	0.4, 1.4	.340

Note: Relative odds adjusted for the variables listed in the table.

* CL = confidence limits.

severity has proved to be less tractable when using only data available from secondary databases.

Numerous valid and reliable measures of stroke severity exist, including the Mathew scale, the Oxbury scale, the National Institutes of Health stroke scale, the Canadian neurological scale, the Orgogozo scale, and the

Scandinavian stroke scale (Cote, Hachinski, Shurvell, et al. 1986; Goldstein, Bertels, and Davis 1989; Mathew, Meyer, Rivera, et al. 1972; Orgogozo 1989; Oxbury, Greenhall, and Grainger 1975; Scandinavian Stroke Study Group 1985). All of these scales, however, require detailed clinical data; these clinical data must be collected either prospectively from the patient on admission or retrospectively through medical record review. Both methodologic approaches are expensive, and may not be cost-effective when conducting preliminary investigations of potential associations.

If a proxy indicator of stroke severity could be identified from among the variables that are typically present in existing hospital discharge and other administrative databases, more meaningful as well as more cost-efficient analyses of the clinical management and outcomes of stroke patients could be conducted using these databases. While detailed clinical data are virtually never included in administrative databases, procedures received by the patient usually are present, although only a limited number may be recorded. Major procedures, such as those essential for patient survival, or expensive procedures, may be the most likely to be included. Use of mechanical ventilation is such a procedure.

With data from a nationally representative sample of hospitalized Medicare patients, we have now shown that a stroke patient's use of mechanical ventilation beginning on the initial day of hospitalization is a reasonable proxy indicator of coma. Level of consciousness on admission is one of the most elegant and valid clinical indicators of severe stroke (Oxbury, Greenhall, and Grainger 1975). Early use of mechanical ventilation was also associated with various alternative, but even less direct, indicators of severity, including admission through the emergency room, admission to intensive care, and issuance of DNR orders. Although these indicators are also likely to be associated with the patient's physical health status prior to his or her stroke, with adjustment for comorbid conditions and other potential confounders such as process of care, early initiation of mechanical ventilation continued to be strongly and significantly associated with level of consciousness.

We have also shown that use of mechanical ventilation beginning on the first day of hospitalization is a strong, independent prognostic indicator. Patients who received mechanical ventilation on admission were substantially more likely to die while in the hospital than other patients. The relative odds of in-hospital death associated with early mechanical ventilation were similar to those associated with being comatose on admission. The association held after adjustment for factors that may influence either patterns of care or patient outcomes, including patient demographics, stroke type, quality

of care, and indicators of prior physical health status, such as comorbid conditions. Moreover, the association between use of mechanical ventilation on the first day of hospitalization and length of stay was consistent with more severe stroke. Among patients who died in the hospital, those who received mechanical ventilation on the first day of hospitalization had shorter lengths of stay while among patients discharged alive, they had longer lengths of stay.

Methodologic studies of risk adjustment have often suggested that it is preferable for measures of severity to be clinical measures of sickness rather than a record of the patient using a service (e.g., using mechanical ventilation), because the use of a service might reflect the quality of care delivered to the patient rather than clinical severity (Park, Brook, Kosecoff, et al. 1990). For example, a relationship between use of a mechanical ventilator and poor outcome (e.g., death) could reflect substantial illness at the time of hospital admission that necessitates the use of a ventilator or, alternatively, it could reflect poor care being delivered to the patient. We restricted our measure of severity to use of mechanical ventilation on the first day of hospitalization in order to minimize the chance that use of a ventilator reflected poor process rather than disease severity at admission (Grotta, Pasteur, Khwaja, et al. 1995; Barnett et al. 1992). Two major causes of respiratory failure in stroke patients that are related to poor quality of care (i.e., oral feeding of patients who are likely to aspirate and use of sedatives that might suppress respiration in patients with impaired consciousness) are not likely to occur during the initial day of hospitalization. Most stroke patients have orders written for "npo" (nothing per orum) during the first day of hospitalization to avoid the risk of aspiration. Additionally, because stroke may remain in evolution during the first day of hospitalization, it is usual practice for many clinicians to avoid sedating these patients on admission. Consequently, inappropriate oral feeding or use of sedatives that could cause respiratory failure and necessitate the use of mechanical ventilation in a stroke patient is much more plausible later in the hospital stay. While we recognize that measuring severity by use of services may reflect quality of care or considerations not related to severity (e.g., race and gender) (Kahn, Pearson, Harrison, et al. 1994; Pearson, Kahn, Harrison, et al. 1992) we believe that in specific clinical circumstances, such as those that typically occur for stroke patients, severity (i.e., the probability that a condition will predict a specified outcome of interest) may be appropriately measured by the use of critical services such as mechanical ventilation.

It is worth noting, though, that even when the use of mechanical ventilation was more liberally defined as the use of this service in the first three days of hospitalization ($n = 144$), our findings were not significantly different

from those reported. (Results are available from the authors on request.) Use of mechanical ventilation continued to perform well as a proxy indicator of coma.

However, a number of other limitations in the data indicate the need for caution in interpreting the findings, although we believe that none of the limitations is sufficient to invalidate them. A major limitation is that this is a secondary analysis of data that were not collected to evaluate potential proxy indicators of stroke severity. Consequently, we did not have available all of the clinical data that are required to construct each of the various measures of stroke severity and, hence, we could not validate use of mechanical ventilation against these preferred indicators of stroke severity (Cote, Hachinski, Shurvell, et al. 1986; Goldstein, Bertels, and Davis 1989; Mathew, Meyer, Rivera, et al. 1972; Orgogozo 1989; Oxbury, Greenhall, and Grainger 1975; Scandinavian Stroke Study Group 1985). However, we did have data on level of consciousness on admission; level of consciousness is a simple but valid indicator of stroke severity and one that is widely used (Goldstein and Matchar 1994; Oxbury, Greenhall, and Grainger 1975). Thus, to the extent that coma in stroke patients reflects severe stroke, the use of mechanical ventilation during the first day of hospitalization is a proxy indicator of severe stroke.

Second, our proposed proxy indicator is crude, able only to distinguish between comatose versus noncomatose stroke patients; that is, it identifies the most severe stroke patients at best. The sensitivity of the indicator was low although its specificity was very high; thus, the use of mechanical ventilation rules in coma but the absence of use does not rule it out. Hence, the interpretation of this proxy indicator may be as an indicator of the most severe stroke versus relatively less severe stroke. Still, the greatest difference in patient outcomes and perhaps degree of physician discretion in use of care is more likely to be found between these two categories of stroke severity.

Third, the data were from medical record review and, therefore, are subject to the limitations that are typical of such data. For example, there may be miscoding or omission of information either within the medical record itself or when the data are abstracted into a hospital discharge database (Leibson et al. 1994; Lloyd and Rissing 1985). The data used in this study were collected rigorously to protect against erroneous coding or data omission; for example, interrater reliability was ascertained and found to be high (Draper, Kahn, Reinisch, et al. 1990; Kahn, Draper, Keeler, et al. 1992). However, we were unable to protect against failure of medical personnel to record data on the care provided to the patient. Moreover, it is unclear if the recording of data will be less comprehensive as a consequence of changes in

reimbursement mechanisms; that is, full recording of the process of care may be diminished when reimbursement is based on a prospectively established payment scale for a diagnostic-related grouping of conditions rather than on actual services provided. It follows that in those databases where the use of mechanical ventilation is not known to be accurately and consistently recorded, the usefulness of this proxy indicator is limited because of potential misclassification bias.

With due regard for the limitations in this study, we conclude that a stroke patient's use of mechanical ventilation on the first day of hospitalization is a useful proxy indicator of coma and is also a prognostic indicator. Moreover, because we studied a nationally representative population of hospitalized stroke patients, these findings are likely to be broadly generalizable to stroke patients in the United States. When using the large, extant administrative databases that are widely available, studies can incorporate this proxy indicator of very severe stroke in their analyses in order to generate more informative results.

Administrative databases, in general, represent a potential resource for generating cost-effective results regarding patterns and outcomes of care. However, the potential of this resource could be enhanced if these databases routinely included information that directly indicated disease severity or, at least, information that could be used as a proxy indicator of severe disease, such as level of consciousness on admission. A less desirable but clearly feasible approach is to include data on the timing of procedures and services. Currently, the Department of Veterans Affairs maintains a national hospital discharge database that includes, for every hospitalization at a VA facility, the procedures, services, and surgeries utilized and the dates on which they were initiated or performed. As we have shown, a valid indicator of coma on admission can be constructed from data on the use and timing of mechanical ventilation. Data on the use and timing of other services or procedures may lend themselves to the construction of proxy indicators of severity for other diseases.

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