

ONLINE FIRST

Population-Based Analysis of Morbidity and Mortality Following Surgery for Intractable Temporal Lobe Epilepsy in the United States

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Objective: To assess the morbidity of temporal lobe epilepsy (TLE) surgery on a nationwide level in order to address reservations regarding the morbidity of anterior temporal lobectomy (ATL) for TLE despite class I evidence demonstrating the superiority of ATL over continued medical therapy.

Design: Retrospective cohort study.

Setting: The Nationwide Inpatient Sample from 1988 to 2003 was used for analysis.

Patients: Only patients who were admitted for ATL for TLE (*International Classification of Diseases, Ninth Revision, Clinical Modification* codes 345.41 and 345.51; primary procedure code, 01.53) were included.

Main Outcome Measures: Morbidity and mortality. Analysis was adjusted for several variables including patient age, race, sex, admission type, primary payer for care, income in zip code of residence, and hospital volume of care.

Results: Multivariate analyses revealed that the overall morbidity (postoperative morbidity and/or adverse dis-

charge disposition) following ATL for TLE was 10.8%, with no mortality. Private insurance decreased postoperative morbidity (odds ratio [OR]=0.52; 95% confidence interval [CI]=0.28-0.98; $P=.04$) and adverse discharge disposition (OR=0.31; 95% CI=0.12-0.81; $P=.02$). Increased patient age increased postoperative morbidity (OR=1.04; 95% CI=1.01-1.07; $P=.03$) and adverse discharge disposition (OR=1.08; 95% CI=1.02-1.13; $P=.004$). Neither sex, income, race, nor hospital volume was predictive of postoperative morbidity. The degree of medical comorbidity directly correlated with the incidence of postoperative morbidity.

Conclusions: Morbidity following ATL for TLE is low throughout the United States regardless of sex, race, insurance status, or income. Younger age and private insurance status are independently predictive of reduced postoperative morbidity. In patients with low medical comorbidity, ATL for TLE is safe, with low morbidity and no mortality.

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ACCOUNTING FOR APPROXIMATELY 1% of the global burden of disease due to disability, with a burden of illness similar to that of lung cancer in men and breast cancer in women, epilepsy affects 0.5% to 1% of the world's population and is the second leading cause of mental health disability in the United States.¹⁻³ Despite the efficacy and availability of antiepileptic drugs, as many as 40% of patients with epilepsy will continue to have seizures even after at least 2 adequate trials of antiepileptic drugs; this accounts for more than 75% of the cost of epilepsy in the United States.⁴⁻⁷

Temporal lobe epilepsy (TLE) is both the most common form of epilepsy and the most likely to remain refractory to medication.^{8,9} Patients with intractable TLE often benefit from surgical management via temporal lobectomy. Results from sev-

eral observational studies and the only randomized controlled trial all demonstrate that surgical intervention is far superior to continued medical treatment in this patient population.^{1,10} Unfortunately, despite these data, only a small number of patients are referred for epilepsy surgery evaluation, most of whom have already had many years of seizures.¹⁰⁻¹²

A possible impediment to increased referrals for epilepsy surgery evaluation may be the perceived degree of morbidity and mortality following temporal lobectomy. To address this issue on a nationwide level, a large inpatient database was used to evaluate the overall morbidity following temporal lobectomy for intractable TLE in the United States over an extended period. Subset analyses of morbidity were performed to assess the existence of racial disparities among this patient population because racial disparities have re-

Table 1. Clinical Characteristics of the 736 Adult Patients With Intractable Temporal Lobe Epilepsy From 1988 Through 2003 Who Received Anterior Temporal Lobectomy

Characteristic	%
Patient age, y	
Mean (SD)	34.8 (9.8)
Median (range)	34.0 (18-72)
Female	53.4
Race	
African American	4.4
Hispanic	5.6
Others	90.0
Primary payer	
Private insurance	61.6
All others	38.4
Caseload of hospital, bed size	
Large	70.1
Small or medium	29.9
Region of hospital	
Northeast	17.3
North Central	20.7
South	30.0
West	32.1
Admission type	
Routine, birth and others	95.0
Emergency/other/facility/court/law	5.0
Surgeon volume ^a	
Low	33.6
High	66.4
Median income ^b	
1	15.4
2	25.6
3	22.2
4	38.8

Median Income \$	1988-1997	1998-2002	2003
1	0-25 000	0-24 999	0-35 999
2	25 001-30 000	25 000-34 999	36 000-44 999
3	30 001-35 000	35 000-44 999	45 000-59 999
4	≥35 001	≥45 000	≥60 000

^aSurgeon volume is defined as low if the operating surgeon performed only 1 or 2 temporal lobectomies per year and high if the surgeon performed 3 or more surgeries per year. The surgeon volume in this data set ranged from 1 to 17, with a median of 3.0 and a mean (SD) of 5.1 (4.2).

^bThe median income has difference ranges across years.

cently been reported regarding access to surgical treatment for intractable TLE.^{13,14}

METHODS

DATA SOURCE

The Nationwide Inpatient Sample (NIS) hospital discharge database (overview available at <http://www.hcup-us.ahrq.gov/nisoverview.jsp>) covering 1988 through 2003, obtained from the Healthcare Cost and Utilization Project, Agency for Healthcare Research and Quality (Rockville, Maryland), was used as the data source for this study.¹⁵ The NIS represents approximately 20% of all inpatient admissions to nonfederal hospitals in the United States. For these years, the NIS contains data on 100% of discharges from a stratified random sample of nonfederal hospitals in 8 to 35 states (number of states increased year to year from 1988-2003), approximating a 20% represen-

tative subsample of all US nonfederal hospital discharges. Because the NIS contains data on all patients discharged from sampled hospitals during the year (regardless of payer or patient age), it can be used to obtain the annual total volume of specified procedures at individual hospitals. Additionally, the surgeon who performed the principal procedure following admission is identified by a unique masked code.

INCLUSION AND EXCLUSION CRITERIA

The NIS database was searched to identify an admission to undergo temporal lobectomy for intractable TLE. Admissions having a patient age of 18 years or older, a diagnosis code of 345.41 (intractable partial epilepsy with impairment of consciousness) or 345.51 (intractable partial epilepsy with mention of impairment of consciousness), and a primary procedure code of 01.53 (brain lobectomy) were included.

CHARACTERISTICS OF PATIENTS

In addition to race, patient age, sex, median household income for postal (zip) code of residence, primary payer (Medicare, Medicaid, private insurance, self-pay, no charge, or other), type of admission (emergency, urgent, or elective), and admission source (emergency department, transfer from another hospital, transfer from long-term care, or routine) were coded in the NIS data. The subset analysis focused on comparisons between that subset and nonsubset persons included (eg, Hispanic vs non-Hispanic); any patient with missing race was viewed as white.

PROVIDER AND HOSPITAL CHARACTERISTICS

The number of available beds (small, medium, large), teaching status, hospital region (Northeast, Midwest, South, West), and location (rural, urban) were coded in the NIS data. Surgeon volumes of anterior temporal lobectomy (ATL) for intractable TLE were derived by counting the cases for each identified surgeon in the database. Surgeon volume was analyzed as either low caseload (<3 ATL per year) or high caseload (≥3 ATL per year).

STATISTICAL ANALYSIS

The characteristics of patients, providers, and hospitals were summarized by descriptive statistics. Results were expressed as mean (standard deviation, median, and range) for continuous variables and frequency (percentage) for categorical variables. Rao-Scott modified χ^2 tests for the univariate comparisons were performed on the categorical variables using PROC SURVEYFREQ from SAS version 9.1 (SAS Institute, Cary, North Carolina). To examine the association between the outcomes of postoperative morbidity or adverse discharge disposition and the characteristics of patient age, sex, race, payer, admission type, income, and caseload of hospital, we first fitted a separate logistic regression model for each characteristic against the outcome and reported the odds ratio (OR) with 95% confidence interval (CI) for each characteristic. We then fitted a multiple logistic regression model on the outcome with the aforementioned characteristics as covariates and reported the adjusted ORs with 95% CIs for each characteristic in the multivariate analysis. Extrapolations to the entire US population were adjusted for the NIS stratified survey method in the logistic regression models by using PROC SURVEYLOGISTIC in the SAS statistical software program. All probability values shown are 2-tailed. A *P* value less than .05 was accepted as significant.

Patients were evaluated examining TLE as a primary diagnosis, 1 of the top 3 diagnoses, and 1 of the top 15 diagnoses. Overall morbidity was evaluated as a summation of postopera-

Table 2. Examination of General Medical Comorbidity in Patients Receiving Anterior Temporal Lobectomy for Intractable Temporal Lobe Epilepsy From 1988 Through 2003 Using a Medical Comorbidity Score Derived From 25 Comorbidity Markers^a

	Comorbidity Score, %				
	0	1	2	3	>3
Proportion of patients	82.3	15.0	2.2	0.5	0
Incidence of postoperative morbidity	7.8	8.2	12.5	25.0	NA

Abbreviation: NA, not applicable.

^aRange, 0-25. The majority of patients had no comorbidities; the incidence of postoperative morbidity directly correlated with increasing comorbidity.

tive morbidity, in-hospital mortality, and adverse discharge disposition. Adverse discharge disposition was defined as hospital discharge to any place other than home (eg, short-term rehabilitation, long-term rehabilitation, hospice).

For subset analysis, ORs were assessed for in-hospital mortality, postoperative morbidity, and adverse discharge disposition individually and in combination for assessment of morbidity. Potential complications of temporal lobectomy were identified using the following codes: postoperative neurological complications (including those secondary to infarction or hemorrhage), 997.00 to 997.09; hematoma complicating a procedure, 998.1 to 998.13; bilateral visual field defects, 368.46 and 368.47; diplopia, 368.2; postoperative infection, 998.5, 998.51, and 998.59; hydrocephalus, 331.3 to 331.4; ventriculostomy placement, 02.2; deep vein thrombosis, pulmonary embolism, or inferior vena cava filter placement, 415, 415.11 to 415.19, 453.8, 453.9, and 38.7; and transfusion of packed red blood cells, 99.04. The effect of general medical comorbidity was assessed using a set of 25 medical comorbidity markers previously described, which were tabulated to provide a single comorbidity score ranging from 0 to 25.^{16,17}

RESULTS

From 1988 through 2003, the NIS database contained 10 723 admissions for adults with intractable TLE, of whom 736 received ATL. Patients were treated at a total of 190 hospitals; 70% of hospitals were classified as large bed size, and approximately two-thirds received care by a surgeon performing at least 3 temporal lobectomies per year; the remaining clinical characteristics are depicted in **Table 1**. Information on the treating surgeon was available for 51.8% of the admissions, with 84 treating surgeons identified in the database. The vast majority of patients receiving ATL had no medical comorbidities, and fewer than 3% had more than 1 comorbidity (**Table 2**). No patient receiving ATL had a comorbidity score higher than 3.

Of the 677 patients with available discharge data, 3 required short-term rehabilitation and 24 required long-term rehabilitation, yielding a total adverse discharge disposition of 4% (27 of 677). The incidence of postoperative morbidity was 8% (**Table 3**). Of the postoperative complications following ATL for TLE, the most common was postoperative neurological complications (2.7%), followed by transfusion of packed red blood cells (2.3%), hematoma (1.2%), homonymous or heteronymous hemianopsia (1.1%), postoperative infection (0.8%), diplopia (0.7%), hydrocephalus (0.4%), and ventriculostomy placement (0.1%). No patient had a deep vein thrombosis or pulmonary embolism or required inferior vena cava filter placement, and there was no mor-

Table 3. In-Hospital Morbidity (Postoperative Morbidity and/or In-Hospital Mortality) in Patients Receiving Anterior Temporal Lobectomy for Intractable Temporal Lobe Epilepsy in the United States From 1988 Through 2003

	%
Mortality	None
Postoperative neurological complications (including those secondary to infarction or hemorrhage)	2.7
Transfusion of packed red blood cells	2.3
Hematoma	1.2
Homonymous/heteronymous hemianopsia	1.1
Postoperative infection	0.8
Diplopia	0.7
Hydrocephalus	0.4
Ventriculostomy placement	0.1
DVT/PE/IVC filter placement	None
Total	8.0

Abbreviations: DVT, deep vein thrombosis; IVC, inferior vena cava; PE, pulmonary embolism.

tality (**Table 3**). The incidence of postoperative morbidity directly correlated with increasing patient comorbidity score (**Table 2**). The overall morbidity, defined as patients with postoperative morbidity and/or adverse discharge disposition, was 10.8% (73 of 677).

Multivariate analysis revealed that private insurance (OR=0.52; 95% CI=0.28-0.98; $P=.04$) and routine admission type (OR=0.36; 95% CI=0.18-0.73; $P=.005$) independently predicted significantly reduced morbidity (**Table 4**). Conversely, older age independently predicted increased postoperative morbidity (OR=1.04; 95% CI=1.01-1.07; $P=.03$); each year of age affected the likelihood of postoperative morbidity by $[(1.04^{\text{Age of Patient}-\text{Age of Comparison Patient}}) - 1] \times 100$, such that a 40-year-old was 4% more likely to have postoperative morbidity than a 39-year-old, 32% less likely than a 50-year-old, and 48% more likely than a 30-year-old. Neither surgeon volume, hospital bed size, sex, African American race, Hispanic race, or income was predictive of postoperative morbidity (**Table 4** and **Table 5**).

Examination of adverse discharge disposition revealed that only private insurance (OR=0.31; 95% CI=0.12-0.81; $P=.02$) and patient age (OR=1.08; 95% CI=1.02-1.13; $P=.004$) were independently predictive of adverse discharge disposition; each year of age affected the likelihood of adverse discharge disposition by $[(1.08^{\text{Age of Patient}-\text{Age of Comparison Patient}}) - 1] \times 100$. No other variable was predictive of adverse discharge disposition (**Table 6** and **Table 7**).

Table 4. Multivariate Analysis of Association Between Patient Variables and Postoperative Morbidity^a

Characteristic	Adjusted OR (95% CI) ^b	P Value ^b
Patient		
Age (for 1-y increase)	1.04 (1.01-1.07)	.03
Female	1.32 (0.72-2.41)	.38
Hispanic vs others	0.60 (0.08-4.32)	.61
Admission type (routine vs birth and others)	0.36 (0.18-0.73)	.005
Primary payer (private insurance vs other)	0.52 (0.28-0.98)	.04
Median income		
1	1 [Reference]	
2	1.40 (0.50-3.88)	.86
3	2.16 (0.90-5.23)	.12
4	1.52 (0.66-3.50)	.86
Hospital bed size (large vs small or medium)	1.29 (0.55-3.07)	.56

Abbreviations: CI, confidence interval; OR, odds ratio.

^aResults from multivariate analysis are shown. African American race was not independently predictive of postoperative morbidity (not shown).

^bAll ORs and P values were calculated using PROC SURVEYLOGISTIC in SAS (version 9.1; SAS Institute, Cary, North Carolina).

Table 5. Univariate Analysis of Association Between Patient Variables and Postoperative Morbidity in US Patients Receiving Anterior Temporal Lobectomy for Intractable Temporal Lobe Epilepsy From 1988 Through 2003^a

Characteristic	OR (95% CI) ^b	P Value ^b
Patient		
Age (for 1-y increase)	1.04 (1.01-1.06)	.004
Female	1.41 (0.90-2.20)	.13
African American vs non-African American	0.97 (0.20-4.75)	.97
Hispanic vs non-Hispanic	0.53 (0.09-3.18)	.48
Admission type (routine vs birth and others)	0.39 (0.20-0.74)	.004
Primary payer (private insurance vs other)	0.76 (0.44-1.30)	.32
Median income		
1	1 [Reference]	
2	1.62 (0.67-3.94)	.61
3	1.85 (0.85-4.03)	.23
4	1.39 (0.66-2.92)	.89
Hospital bed size (large vs small or medium)	1.56 (0.81-3.03)	.19
High surgeon volume (≥ 3 surgeries/y)	1.05 (0.58-1.90)	.87

Abbreviations: CI, confidence interval; OR, odds ratio.

^aResults from univariate analysis are shown.

^bAll ORs and P values were calculated using PROC SURVEYLOGISTIC in SAS (version 9.1; SAS Institute, Cary, North Carolina).

Table 6. Univariate Analysis of Association Between Patient Variables and Adverse Discharge Disposition in Patients Receiving Anterior Temporal Lobectomy for Intractable Temporal Lobe Epilepsy in the United States From 1988 Through 2003^a

Characteristic	OR (95% CI) ^b	P Value ^b
Patient		
Age (for 1-y increase)	1.06 (1.03-1.10)	.001
Female	1.34 (0.62-2.88)	.46
African American vs non-African American	1.31 (0.16-10.5)	.80
Admission type (routine vs birth and others)	0.75 (0.05-10.4)	.83
Primary payer (private insurance vs other)	0.54 (0.24-1.24)	.15
Median income		
1	1 [Reference]	
2	2.53 (0.54-11.9)	.46
3	1.60 (0.20-13.0)	.82
4	2.96 (0.69-12.7)	.17
Hospital bed size (large vs small or medium)	2.25 (0.81-6.28)	.12
High surgeon volume (≥ 3 surgeries/y)	1.56 (0.56-4.38)	.40

Abbreviations: CI, confidence interval; OR, odds ratio.

^aResults from univariate analysis are shown.

^bAll ORs and P values were calculated using PROC SURVEYLOGISTIC in SAS (version 9.1; SAS Institute, Cary, North Carolina).

Table 7. Multivariate Analysis of Association Between Patient Variables and Adverse Discharge Disposition^a

Characteristic	Adjusted OR (95% CI) ^a	P Value ^a
Patient		
Age (for 1-y increase)	1.08 (1.02-1.13)	.004
Female	1.39 (0.54-3.57)	.49
African American vs others	1.11 (0.12-10.1)	.93
Admission type (routine vs birth and others)	0.73 (0.06-8.49)	.80
Primary payer (private insurance vs other)	0.31 (0.12-0.81)	.02
Median income		
1	1 [Reference]	
2	1.96 (0.38-10.2)	.76
3	1.96 (0.18-15.9)	.98
4	2.56 (0.55-12.0)	.32
Hospital bed size (large vs small or medium)	1.07 (0.34-3.33)	.92

Abbreviations: CI, confidence interval; OR, odd ratio.

^aResults from multivariate analysis are shown.

^bAll ORs and P values were calculated using PROC SURVEYLOGISTIC in SAS (version 9.1; SAS Institute, Cary, North Carolina).

COMMENT

Despite the success of temporal lobectomy in the treatment of intractable TLE, a large majority of patients with TLE are not referred for epilepsy surgery evaluation.^{10,11} Although previous analysis of a large number of temporal lobectomy series places the risk of permanent postoperative morbidity at 1% to 10% (without including ad-

verse discharge disposition), there may be a reticence among some providers to refer patients for surgical intervention.^{10,18} Furthermore, recent studies have indicated that racial disparities exist with regard to access to temporal lobectomy among patients with TLE.^{13,14} Consequently, this study sought to evaluate the morbidity of temporal lobectomy on a nationwide scale and to assess the presence or absence of health care disparities in post-surgical morbidity.

The findings of this study reveal that the incidence of postoperative morbidity following temporal lobectomy for TLE is 8%, well within the range quoted by several studies, and includes several complications that may be transient in nature. The incidence of adverse discharge disposition is 4%, and the overall morbidity (postoperative morbidity and/or adverse discharge disposition) is 10.8%, with no mortality. The risk of postoperative morbidity increases with increasing medical comorbidity and independently increases with increasing patient age, lack of private insurance, and nonroutine hospital admission.

As intriguing as these results are, it is important that they be tempered by the limitations of this study. The first and most obvious limitation is the retrospective nature of the study, which necessitated the use of ORs instead of relative risk for statistical interpretation of the data. The second limitation is the incompleteness of the NIS in representing the United States; although it is by far the most comprehensive database available spanning 1988 to 2003, it only represents 20% of all inpatient admissions in the United States and does not include federal hospitals. Another limitation is the inpatient nature of the database, which limits the ability of this study to identify delayed postoperative complications. A fourth limitation is that the nature of the database limits the ability of this study to determine whether morbidity results in transient or permanent postoperative deficits. Finally, because more than 99% of patients in this study had fewer than 3 medical comorbidities, the results from this study should not be applied universally without regard to a prospective patient's underlying comorbidity status.

Despite the limitations of this study, the results shed light on an important fact: temporal lobectomy for intractable TLE in the United States had low morbidity, with no mortality over a 16-year period. This finding, in combination with those of several other studies, confirms that ATL should be viewed by the general medical and societal community as safe and that patients with intractable TLE should be referred for epilepsy surgery evaluation, particularly if they have 3 or fewer medical comorbidities. Furthermore, because neither African American nor Hispanic race predisposes toward increased postoperative morbidity, increased measures should be taken to address previously reported racial disparities in access to ATL.^{13,14}

Morbidity following temporal lobectomy for intractable TLE in the United States is low and should not preclude patients with TLE from being referred for epilepsy surgery evaluation regardless of sex, race, insurance status, or income. Medical comorbidity correlates with the incidence of postoperative morbidity. Younger age and private insurance status independently predict decreased postoperative morbidity and better hospital discharge disposition.

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Author Contributions: Dr McClelland had full access to all of the data in the study and takes responsibility for the integrity of the data and the accuracy of the data analysis. *Study concept and design:* McClelland, Guo, and Okuyemi. *Acquisition of data:* McClelland and Okuyemi. *Analysis and interpretation of data:* Guo and Okuyemi. *Drafting of the manuscript:* McClelland, Guo, and Okuyemi. *Critical revision of the manuscript for important intellectual content:* McClelland, Guo, and Okuyemi. *Statistical analysis:* Guo. *Obtained funding:* Okuyemi. *Administrative, technical, and material support:* Okuyemi. *Study supervision:* McClelland.

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