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GEORGIA STATE UNIVERSITY, SCHOOL OF PUBLIC HEALTH

QUALITY IMPROVEMENT IN STROKE CARE AND ITS
IMPACT: THE GEORGIA COVERDELL ACUTE STROKE
REGISTRY EXPERIENCE

by
MOGES SEYOUM IDO
MD, MS, MPH

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of
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DOCTOR OF PHILOSOPHY IN PUBLIC HEALTH

ATLANTA, GEORGIA
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COVERDELL ACUTE STROKE REGISTRY EXPERIENCE

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Date : June 22, 2016

Author's Statement Page

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Moges Seyoum Ido

Signature of Author

TO MY PARENTS:

GHENET BALCHA WURGI

SEYOUM IDO BORU

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ABSTRACT

QUALITY IMPROVEMENT IN STROKE CARE AND ITS IMPACT: THE GEORGIA COVERDELL ACUTE STROKE REGISTRY EXPERIENCE

by

MOGES SEYOUM IDO, MD, MS, MPH

June 22, 2016

The Georgia Department of Public Health has been engaged in a registry-based quality improvement initiative to monitor and improve the quality of stroke care. It is important to evaluate effectiveness of the quality improvement initiative in order to expand the effort to other sites or disease conditions. The studies, included in this dissertation, addressed whether acute ischemic stroke patients cared for by hospitals participating in the Georgia Coverdell Acute Stroke Registry (GCASR) had a better survival than those treated at other facilities, assessed whether quality of care as measured by nationally accepted ten performance measures is associated with improved patient outcome and evaluated the impact of intravenous alteplase treatment on 1-year mortality.

Three data sources – GCASR, Georgia Discharge Data System and the death data – were used for analyses. These data sources were linked applying both a hierarchical deterministic and a probabilistic linkage methods. Survival after stroke incident was analyzed using the extended Cox proportional hazard model. Generalized estimating equation (glimmix procedure) and conditional logistic regression were applied, respectively, to assess the association of quality of care and intravenous alteplase use with 1-year mortality.

Acute ischemic stroke patients treated at nonparticipating facilities had a hazard ratio for death of 1.14 (95% confidence interval, 1.03–1.26; *P-value* = .01) after the first week of admission compared with patients cared for by hospitals participating in the registry. Among patients treated in GCASR-participating hospitals, patients who received the lowest and intermediate quality care respectively had a 3.94 (95%CI: 3.27, 4.75; p-value <0.0001) and a 1.38 (95%CI: 1.12, 1.62; p-value=0.002) times higher odds of dying in one year compared to those who got the best quality stroke care. Patients who were eligible but did not receive IV alteplase had a 1.49 (95%CI: 1.09-2.04; p-value=0.01) times higher odds of dying within one year than those who were treated with the thrombolytic agent.

The results strongly suggest that registry-based quality improvement effort has brought significant improvements in ischemic stroke patients' outcomes. Therefore, it is critical that hospitals adopt a quality improvement strategy to change the process of care delivery for a better patient outcome.

CHAPTER I

INTRODUCTION

Quality Improvement

Healthcare providers strive to improve the quality of patient care and enhance their performance. The assessments and continuous systematic efforts to improve quality of care constitute *quality improvement*.¹ Quality improvement is data driven, focuses on patients' need and expectations, and works on processes and systems of healthcare delivery.¹ In most healthcare setups, particularly where multiple units play a role in the process of healthcare delivery, it requires a team effort involving every unit of the organization to improve the quality of patient care.

The Institute of Medicine (IOM) defines quality of care as “the degree to which health services for individuals and populations increase the likelihood of desired health outcomes and are consistent with current professional knowledge.”² Quality of care encompasses every aspect of healthcare – diagnostic, therapeutic and preventive – both in a clinical and community setup. Delivery of a clinical care has three dimensions: the environment in which the care is provided (the structure); the actual care including patient reception, diagnosis, treatment, preventive care and discharge instruction; and the outcome in terms of patient health status, satisfaction, and behavior and resource consumption.³ Measurement of the factors in each dimension of care delivery may not be sufficient to evaluate quality of care unless they can be shown to relate to indices of quality.

The IOM's definition implies that quality is inherent to any health service and the care has to be congruent with the best available evidence-based practices and guidelines. Adherence to these guidelines need to be monitored continuously to ensure that patients receive the best care at all times. Measuring healthcare providers' performance requires continuous systematic data collection and analysis, and performance measures to assess whether the provider is attaining the goal set for healthcare delivery process.

Despite rapid advances in medical science and technology, not all patients consistently receive high quality clinical care. A study among American adults in 12 metropolitan cities indicated that patients received only 55% of the recommended care.⁴ Almost two decades after FDA approved the use of thrombolytics for ischemic stroke patients, only 12% of the patients receive the treatment in Georgia.⁵ Thus, medical advances and the availability of resources do not necessarily translate into provision of high quality care to all patients over time. It is, therefore, necessary to design strategies for dissemination and broad scale application of evidence based clinical practices. How states organize their healthcare system or how healthcare providers set up delivery of care taking a system's perspective becomes important in meeting patients' expectation and expectations of the community at large.

Replication and implementation of an intervention require demonstration of effectiveness in a broader use. Despite evidence of effectiveness, hindrance to implementation could come from lack of information about the new strategy on quality of care or from reluctance to accept the new clinical care guidelines.⁶⁻⁸ Strong evidence demonstrating the effectiveness of an intervention would facilitate buy-in from healthcare facilities and their practitioners. Therefore, it

is essential to measure, evaluate and document the changes brought by interventions targeting quality of care and its purported impact on patient outcomes.

Strategies to implement evidence based medicine has evolved from the optimistic passive diffusion where we assume clinicians would adopt a new clinical practice if they are provided with the information to a more active approach of quality improvement.⁹ The concept of quality improvement is not unique for clinical care or healthcare in general; rather, the industrial sector is the vanguard in implementing methods of quality improvement for better productivity (efficiency) and ensuring product quality.¹⁰ Methods of quality improvement tried and tested in other sectors have also been shown to be applicable in clinical care^{11,12} as well because the ultimate target remains the same – better outcome in the most efficient way.

Studies have shown that implementation of quality improvement activities lead to improvement in the process of care delivery and patient's outcomes.¹³⁻²³ These studies involved healthcare facilities of different levels and various clinical conditions from infectious disease to chronic conditions such as depression and diabetes mellitus. They documented improvements in adoption of care processes and uptake of evidence-based guideline recommendations including prescription of appropriate medications, reduction in unnecessary referrals, narrowing the gap in gender and racial disparity in health outcomes, reducing complications, secondary disease prevention and better patient outcomes in terms of disease control, readmission rate and mortality.

Some studies, however, failed to demonstrate significant improvement both in patient care process and outcome resulting from QI activities.²⁴⁻²⁶ A review of literature on the impact of quality improvement initiatives concluded that the effect of a quality improvement undertaking

cannot be predicted with certainty.²⁴ The reviewers examined 72 papers from 1,101 published on quality improvement from 1995 to 2006, and were only able to show that quality improvement collaborative would improve care process, organizational performance, access to care and consumer satisfaction but not the outcome. Therefore, it is important to evaluate such initiatives using outcome measures both for the purpose of long-term, large scale implementation and for identifying components of the quality improvement initiative with the greatest relationship to those outcomes, even if they were launched initially based on available scientific evidences.

In the context of clinical care, ensuring clinicians adhere to evidence-based clinical guidelines is part of a quality improvement task. Guidelines usually are institution-based, but in some cases there are guidelines developed by experts or professional associations that are also endorsed and recommended by national institutions. It is expected that such guidelines would be readily disseminated to healthcare providers and easily adopted, although the environment in which the care is provided and the processes involved in implementing national guidelines must be considered. However, the basic question –whether or not adherence to clinical guidelines in stroke care results in better patient outcome – remain unanswered.

The Georgia Coverdell Stroke Registry

Stroke is the fifth leading cause of mortality in the United States.²⁷ Every year, around 800,000 people develop acute stroke²⁸ and about 70% of the survivors develop some residual disability including neurological deficit, speech disorder, cognitive deficit or psychological disorder such as depression.²⁹ Stroke not only affects the individual patient but adds economic and emotional burden to their caregivers and the community at large.^{30,31} In the United States, the direct and indirect costs of stroke amounted to 36.5 billion dollars in 2010.²⁸

In 2001, the United States Congress directed the Centers for Disease Control and Prevention (CDC) to establish a state-based acute stroke registry to measure and monitor the quality of acute stroke patient care.³² After three years of piloting, the state of Georgia received a grant to set-up a registry which is currently housed in the Department of Public Health (DPH). Since then, DPH, in collaboration with its partners, has been assisting more than 60 hospitals to improve the quality of stroke patient care. Different size hospitals ranging from critical access to large teaching hospitals participate in the registry; currently, about 80 percent of stroke patients are treated at GCASR participating hospitals.

A wealth of scientific evidences shows that improvement in specific elements of clinical care could result in better patient outcome.³³ The Georgia Coverdell Acute Stroke Registry (GCASR) encourages hospitals to adopt a quality improvement program and provides technical assistance through regular trainings, workshops, site visits and direct one-on-one consultations, data feed-back, mentorship and sharing the best practices to ensure that every patient in Georgia receives the best evidence-based clinical care.

The Institute of Medicine's definition of quality of care puts emphasis on health outcome as indicators of quality, although information on the type, level and amount of healthcare provided to the community is also essential. Outcome measures may not be as sensitive as process measures in showing immediate changes made in quality improvement initiatives; however, they are necessary to show that the change in process measures results in benefits to patients.³⁴

STUDY OBJECTIVES

GCASR has registered significant improvements in the quality of care provided in participating hospitals.^{35,36} Based on the 2005-2009 hospital discharge data, ischemic stroke patients cared for by GCASR hospitals had a 64% higher odds (OR=1.64) of receiving intravenous thrombolysis. However, it needed to be seen whether patients cared for by hospitals participating in GCASR had better outcome and if this improvement in patient outcome could be attributed to the quality improvement measures undertaken by the participating hospitals. The main objective of this study, therefore, is to assess the direct impact of the quality improvement program on short and/or long term outcomes – ambulatory status at discharge, readmission and death.

- Objective 1. Do acute ischemic stroke patients treated at GCASR hospitals have a better survival than patients cared for by non-participating hospitals?
- Objective 2. Does quality improvement as measured by the ten performance measures reduces the 1-year mortality of acute ischemic stroke patients?
- Objective 3. Does intravenous alteplase affect mortality among acute ischemic stroke patients?

The results will help to expand the program to non-participating hospitals in Georgia and for other states to learn from and replicate Georgia's experience. The studies required linking three data sources – the GCASR data, the Georgia Discharge Data system (GDDS - hospital discharge data) and the Death Records – related to the care and outcome of stroke patients in Georgia. GCASR and GDDS data from 2008 to 2013 and death data from 2008 to 2014 were linked and analyzed. The data sources have variables on patient demography, disease status,

treatment, facility and event-related information. This experience of linking registry and administrative data will serve as a blue print for evaluation of other public health programs based on clinical care.

CHAPTER II

Administrative Data Linkage to Evaluate a Quality Improvement Program in Acute Stroke Care, Georgia, 2006 – 2009

ABSTRACT

Introduction

Tracking the vital status of stroke patients through death data is one approach to assessing the impact of quality improvement in stroke care. We assessed the feasibility of linking Georgia hospital discharge data with mortality data to evaluate the effect of participation in the Georgia Coverdell Acute Stroke Registry on survival rates among acute ischemic stroke patients.

Methods

Multistage probabilistic matching, using a fine-grained record integration and linkage software program and combinations of key variables, was used to link Georgia hospital discharge data for 2005 through 2009 with mortality data for 2006 through 2010. Data from patients admitted with principal diagnoses of acute ischemic stroke were analyzed by using the extended Cox proportional hazard model. The survival times of patients cared for by hospitals participating in the stroke registry and of those treated at nonparticipating hospitals were compared.

Results

Average age of the 50,579 patients analyzed was 69 years, and 56% of patients were treated in Georgia Coverdell Acute Stroke Registry hospitals. Thirty-day and 365-day mortality

after first admission for stroke were 8.1% and 18.5%, respectively. Patients treated at nonparticipating facilities had a hazard ratio for death of 1.14 (95% confidence interval, 1.03–1.26; *P-value* = .01) after the first week of admission compared with patients cared for by hospitals participating in the registry.

Conclusion

Hospital discharge data can be linked with death data to assess the impact of clinical-level or community-level chronic disease control initiatives. Hospitals need to undertake quality improvement activities for a better patient outcome

INTRODUCTION

Assessing the impact of chronic disease programs and the quality of clinical care for patients with chronic diseases is essential to identify areas for improvement in care and to demonstrate the level and nature of improvements already made.³⁷ The American Heart Association/American College of Cardiology Working Group on Quality of Care and Outcomes Research in Cardiovascular Disease and Stroke advocates measuring the short-term and long-term outcomes of quality of care for stroke patients as a way of determining the impact of related chronic disease programs.³⁸ Tracking the vital status of patients with chronic disease, who may be seen at different health facilities, by using death data is a promising method for assessing the overall quality of care for chronic diseases.³⁷

Administrative data such as hospital discharge data and death data are great resources for public health studies.^{39–41} These are population-based databases that can be used to assess the quality of stroke care because they include all population groups. Administrative data are easy to access, and they provide longitudinal information for passive follow-up and trend analyses.

The Georgia Coverdell Acute Stroke Registry (GCASR) is a part of a national stroke registry program, the Paul Coverdell National Acute Stroke Registry. The national registry has the long-term goal of reducing premature deaths attributable to stroke and preventing stroke disability and recurrent stroke through ensuring the highest quality of acute stroke care to all Americans. GCASR was launched by the Georgia Department of Public Health in 2005 in partnership with other stakeholders. We sought to assess the feasibility of linking mortality data from the Georgia Department of Public Health Office of Vital Records with hospital discharge data from the Georgia Hospital Association's Georgia Discharge Data System (GDDS) and to

evaluate the impact of participation in a state-based registry program on survival of patients with acute ischemic stroke.

METHODS

Georgia death records and Georgia hospital discharge data

The Georgia Department of Public Health Office of Vital Records is responsible for collecting information about deaths among Georgians by using the death certificates. The death certificate contains information on individuals' demographic characteristics, residence, underlying possible causes of death, location of death, and death date. Each year, more than 67,000 Georgians die, and 98% of the deaths occur within the state of Georgia.

The GDDS is housed at the Georgia Hospital Association and has information on all inpatients discharged from nonfederal short-stay hospitals in Georgia. GDDS gathers more than a million records per year. GDDS and mortality data share common variables including age, sex, race, residence information, and a quasi-unique subject identifier (LONGID) that facilitates the data linkage.

The feasibility of data linkage is based on the assumption that the variable LONGID was sufficiently specific to distinguish each subject in the data sources. The LONGID is a 15-digit alphanumeric unique code created from letters of patients' first and last names, birth date, and sex. We tested accuracy of data linkage by using data from GDDS for 1,494 Georgia patients who were admitted to a hospital for acute stroke and who died as a result (*International Classification of Diseases, Ninth Revision* [ICD-9]) codes 430–436) in 2006 and for 3,598 patients with similar age characteristics (patients with malignant neoplasm of respiratory and

intrathoracic organs: ICD-9 codes 160–165) but who were alive in 2006. Patients with similar age characteristics were chosen because personal name patterns in a given community may change through time.

The test data set was then linked with the Georgia mortality data for 2006 by using a multistage deterministic and probabilistic matching algorithm and various combinations of key variables (Table 1 and Table 2). We used fine-grained record integration and linkage software for matching, and we excluded duplicate entries using the LONGID, admission and discharge dates, and facility codes.⁴² Degrees of linkage between hospital discharge data and mortality data were determined (Table 3).

Assessment of impact of stroke registry – survival analysis

We used the 2005 through 2009 GDDS and the 2006 through 2010 Georgia Office of Vital Records mortality data to examine the survival rates of acute ischemic stroke patients. Patients admitted to nonfederal acute care and critical access facilities with the principal diagnosis ICD-9 codes 433 and 434 were identified and linked to the death data. Death and survival time from the index admission date, regardless of the underlying cause of death, were the outcome variables. We believe that care in the first few hours after stroke symptom onset determines the stroke patient's subsequent health condition, so we attributed the outcome to the facility of first stroke admission. Patients were labeled to have had a first stroke admission in 2006 if they were not admitted for any type of stroke, ICD-9 codes 430–438, in 2005.

We defined enrollment in GCASR if the hospital actively participated in data entry and quality improvement activities. We considered patients to have had stroke care by a GCASR

facility if the hospital in which patients were admitted was enrolled in the registry. Patients who were treated at any time before a facility was enrolled or after it withdrew its participation were counted as patients treated by a non-GCASR hospital. We included patient's sociodemographic characteristics such as age, sex, race, insurance status, and length of hospital stay, and hospital features including number of beds and location as covariates in the analysis. On the basis of the number of beds, we classified hospitals as small (<100 beds), medium-small (100–249 beds), medium-large (250–399 beds) and large hospitals (≥ 400 beds). We used the Rural-Urban Commuting Area classification of location to classify hospitals geographically into metropolitan (codes 1–3) and nonmetropolitan (codes >3).⁴³

Comorbidities were included in the analyses to adjust for disease severity. We used the Healthcare Cost and Utilization Project software from the Agency for Healthcare Research and Quality (US Department of Health and Human Services) to define comorbidities for each patient based on the ICD-9 codes in the hospital discharge data.^{44,45} Patients' readmission status before either the end of the follow-up period or the patient's death was captured from the hospital discharge data, and we classified patients as either not having been readmitted, readmitted to the same hospital, or readmitted to a different hospital. If patients were admitted to a different hospital within a day after their index or first admission date we considered their status as a transfer rather than a readmission, and they were excluded from the analysis. All the variables used in the analyses refer to what was documented at the first stroke admission except for the date of death. To have stable estimates, we excluded stroke patients from hospitals with fewer than 15 patients over the study period.

Statistical analysis

We analyzed the data by using SAS for Windows (version 9.3, SAS Institute, Inc). We assessed the sensitivity of the linkage procedure based on the proportion of stroke-related in-hospital deaths that were captured by the 2006 Georgia vital records mortality data. We determined specificity by the proportion of subjects who were admitted in 2007 having a malignant neoplasm of the respiratory organs that were linked to any of the records in the 2006 death file. We assessed patient and hospital characteristics descriptively and tested differences between patients treated at GCASR participating and nonparticipating hospitals using χ^2 tests for nominal variables and Wilcoxon tests for quantitative variables.

We assessed the proportional hazard assumption graphically and through the goodness-of-fit test for correlation between the Schoenfeld residuals and failure time.⁴⁶ We repeated the graphic assessment using the log–negative log of survival curves after adjusting for covariates. The GCASR participation variable did not satisfy the proportional hazard assumption. Thus, we analyzed survival time in correlated data using the extended Cox proportional hazard model with the robust sandwich estimate option to estimate the marginal covariate effects. We performed the analysis with and without censoring at 1 year. Results are presented indicating the hazard ratio for death in the first year after the seventh day of the first stroke admission date by different patient and hospital characteristics, including participation in GCASR.

RESULTS

Data linkage test for accuracy

Of the 1,494 acute stroke patients with an in-hospital death recorded in the 2006 hospital discharge data, 1,381 (92.4%) were identified in the 2006 death data, whereas none of the 3,598 patients with malignant neoplasm of respiratory and intra-thoracic organs diagnosed in 2007 were linked to the 2006 death data. Agreements between hospital discharge records and death data were high (>91%) for demographic variables, facility (93.6%), and discharge or death dates (92.6%) (Table 3).

Impact of participation in state-based stroke registry: survival analysis

From the initial 50,937 patients listed, 358 were excluded because 269 were considered transfers and 89 were from hospitals with fewer than 15 cases. Analysis was performed for 50,579 acute ischemic stroke patients (Table 4) admitted to 131 acute care and critical access hospitals in Georgia to assess the impact of participation in GCASR during 2006 to 2009. Most (52%) were women, and whites accounted for two-thirds (66%) of the patients. The mean age for first stroke admission was 69 years. Most (64%) had Medicare as their principal health insurance coverage. The median hospital length of stay was 3 days.

GCASR-participating hospitals treated 56% of the ischemic stroke patients ($n = 28,077$), and there were no statistical differences in age, hospital length of stay, proportion of various racial groups, or proportion of subjects with insurance coverage between patients treated at GCASR and non-GCASR hospitals (Table 4). However, non-GCASR hospitals were more likely to see female stroke patients, have less than 100 beds, to be in nonmetropolitan areas, and record

more stroke-related deaths at 30 and 365 days following stroke admissions. The overall mortality at 30 days and 365 days after the first admission were 8.1% and 18.5%, respectively.

The extended Cox model indicated that patients treated at non-GCASR hospitals had a hazard ratio of 1.14 (95% confidence interval [CI], 1.03–1.26) from the eighth day after admission to 1 year after admission (Table 5). A similar hazard ratio (1.13; 95% CI, 1.04–1.22) was observed when no cutoff date was applied. Similarly, older patients and those treated in nonmetropolitan hospitals had a higher hazard ratio than their counterparts. Patients with a private insurance or self-pay had a lower hazard ratio than did Medicare patients. In addition, hospitals with fewer than 100 beds and longer hospital stays for patients were independently associated with subsequent death (Table 5).

DISCUSSION

Acute ischemic stroke patients cared for by hospitals participating in GCASR had a better outcome than their counterparts in nonparticipating hospitals. This study found a modest (14%) increase in the hazard ratio for death in the first year for patients treated at non-GCASR participating facilities. Several studies have shown that quality improvement efforts result in improved stroke patient care.^{47–50} This study, however, demonstrated that a state-based initiative based on the collaborative effort of professionals who are willing to share their expertise and exchange best practices results in tangible benefit to the community served.

Patients treated at non-GCASR facilities continued to have the same hazard ratio throughout their follow-up time, indicating perhaps that the clinical care provided to patients at their first stroke episode influenced their risk of mortality in the subsequent years. Regardless of

whether hospitals participated in the GCASR, patient outcomes throughout Georgia improved with time. Compared with patients who had an acute ischemic stroke in 2009, patients during 2006 through 2007 had a 9% higher risk of dying during the first year after the index admission. Development of new treatment guidelines and their implementation by health care providers may have contributed to the reduction in mortality; however, it is impossible to rule out a possible spillover effect of the GCASR initiatives to nonparticipating facilities.

There was no meaningful difference in outcomes among hospitals of different size except for small hospitals (<100 beds) where patients had a 17% higher risk of mortality. Hospitals participating in GCASR tended to be metropolitan and larger, and although our analyses adjusted for these 2 variables, differences attributable to other variables between the 2 hospital groups cannot be ruled out. It is not possible, thus, to associate the reduction in hazard ratio among the GCASR hospitals entirely to the quality improvement initiatives undertaken by the registry. In future studies, linking the registry data (where interventions received by patients are documented) to the hospital discharge and death data will be helpful to associate the clinical care information with patient outcome.

The yield from the linkage procedure was sufficient to assess the impact of the quality improvement program. There would be patients who died but were not picked by the matching procedure; however, failure to link was not related to the type of hospital where patients were treated in the test data set. Failure to link gives a lower estimate of the actual mortality but does not introduce bias in the study's effect measure. Studies elsewhere reported different rates of mortality for ischemic stroke.⁵¹⁻⁵⁵ The mortality at 1 month poststroke admission ranges from 9% in Australian and Israeli studies to 17% in a Rochester, Minnesota, study. Also, the 1-year

mortality has been reported to vary from less than 10% in Japanese and Taiwanese studies to 29% in the Minnesota study. The observed differences may be due to variations in study methodology, population characteristics, and quality of patient care. The 1-year mortality estimate observed in this analysis (18.5%) lies between extreme values that have been reported by other investigators, thus indicating that the linkage procedure was sufficiently sensitive and may even be a reasonable approach to estimate mortality and survival rates across the course of stroke patient care. We believe our estimates may be lower than expected rates because the data linkage may not have captured all patients who died in the given period, particularly those who died outside the state of Georgia.

This study has limitations, some of which are inherent to any method that assesses the effect of a quality improvement intervention. It is difficult to define the time when the effect of such an intervention wanes, and several factors contribute to the overall well-being of a patient through time. Survival of acute ischemic stroke patients depends on factors such as patient and hospital characteristics, the time from symptom onset to arrival at the hospital, disease severity, the quality of service received from the health care facility on first encounter, the quality of rehabilitation services, and the quality of life once the patient is discharged from a hospital. This analysis took into account most of the prehospital discharge factors except for time elapsed between symptom onset and arrival at the hospital. In addition, we did not have information on postdischarge rehabilitation and quality of life.

Although administrative data may lack consistent case definitions from one data set to another and the use of ICD-9 codes may not capture all possible acute stroke patients, the effect of misclassification is minimal in studies addressing the impact of hospitals' participation in a

quality improvement registry, because misclassifications are more likely to be non-differential and would only reduce the effect measure toward the null value. Moreover, this study may not have completely captured disease severity, which is the main predictor of mortality. Different indices, including the National Institute of Health Stroke Scale, have been suggested by researchers to predict mortality, but there is no consensus index.⁵⁶⁻⁶⁰ Each one has its own merit in terms of feasibility of data collection, availability for data collection, and discriminatory power of fatal outcome. Several studies used the comorbidity measure, initially developed by Elixhauser et al⁴⁴ in various disease conditions,⁶¹⁻⁶⁶ and Zhu and Hill have demonstrated its usefulness in stroke as well.⁶⁷ It is, thus, reasonable and practical to use comorbidity measures to account for disease severity.

State-based hospital discharge data and death data can be linked and are excellent for estimating survival or risk for mortality, outcome measures that are helpful to assess the impact of clinical-level or community-level chronic disease control initiatives. The results of this study show that participation in a state-based stroke registry for improving the quality of care is associated with reduced mortality from acute ischemic stroke. Thus, hospitals should be encouraged either to participate in a structured program of quality improvement such as state-based registries or undertake their own quality improvement to provide the best possible evidence-based care to their patients for a better outcome.

Table 1. Algorithm for merging the Georgia Discharge Data System with the Georgia mortality data of the same calendar Year

Linkage Step	Linking Variable	Distance Metric (Approve/Disapprove Level)	Condition Weight, ^a %	Acceptance Level, ^b %
Step I	LONGID ^c	Edit distance (0.05/0.15 ^d)	70	80
	Residence county	Equal fields Boolean distance	15	
	Race	Equal fields Boolean distance	10	
	Sex	Equal fields Boolean distance	5	
Step II	Name ^e	Edit distance (0.15/0.3)	40	80
	Birth date	Date distance (± 0 d)	30	
	Discharge date	Date distance (± 0 d)	20	
	Residence zip code ^f	Equal fields Boolean distance	10	
Step III	Name ^e	Edit distance (0.15/0.3)	40	95
	Age, y	Numeric distance (± 0)	10	
	Discharge date	Date distance (± 0 d)	20	
	Residence zip code ^f	Equal fields Boolean distance	15	
	Race	Equal fields Boolean distance	10	
	Sex	Equal fields Boolean distance	5	
Step IV	Birth date	Date distance (± 0 d)	35	100
	Discharge date	Date distance (± 0 d)	25	
	Residence county	Equal fields Boolean distance	25	
	Race	Equal fields Boolean distance	10	
	Sex	Equal fields Boolean distance	5	

a: Proportional weight for each element in the linkage step.

b: Total match score at which records are considered to be linked.

c: 15-digit alphanumeric code created from letters of patients' first and last names, birth date, and sex.

d: The proportion of mismatched characters used to determine whether the records are considered to be linked.

e: Refers to a 6-digit code derived from names.

f: 5-digit zip code.

Table 2. Algorithm for merging the Georgia Discharge Data System with the Georgia mortality data from different calendar years

Linkage Step	Linking Variable	Distance Metric (Approve/Disapprove Level)	Condition Weight, ^a %	Acceptance Level, ^b %
Step I	LONGID ^c	Edit distance (0.05/0.15)	70	80
	Residence county	Equal fields Boolean distance	15	
	Race	Equal fields Boolean distance	10	
	Sex	Equal fields Boolean distance	5	
Step II	Name ^d	Equal fields Boolean distance	40	81
	Birth date	Date distance (± 0 d)	30	
	Residence zip code ^e	Equal fields Boolean distance	15	
	Race	Equal fields Boolean distance	10	
	Sex	Equal fields Boolean distance	5	
Step III	Name ^d	Edit distance (0.15/0.3)	40	100
	Age	Numeric distance (± 0)	30	
	Residence county	Equal fields Boolean distance	15	
	Race	Equal fields Boolean distance	10	
	Sex	Equal fields Boolean distance	5	

a: Proportional weight for each element in the linkage step.

b: Total of condition weights at which records are considered to be linked.

c: 15-digit alphanumeric code created from letters of patients' first and last names, birth date, and sex.

d: Refers to a 6-digit code derived from names.

e: 5-digit zip code.

Table 3. Agreement in the matching variables of the linked Georgia hospital discharge data and Georgia mortality data

Variable	Agreement, %	
	Test Data and 2006 Death Data	2006–2009 Hospital Discharge and 2006–2010 Death Data
LONGID ^a	85.8	91.3
Birth date	94.5	96.2
Name ^b	91.9	98.3
Sex	99.2	99.8
Age	98.1	__ ^d
Race	95.2	96.8
Residence county	91.0	88.3
Residence zip code ^c	62.0	62.6
Facility	93.6	__ ^d
Discharge date or date of death	92.6	__ ^d

a: 15-digit alphanumeric code created from letters of patients' first and last names, birth date, and sex.

b: Refers to a 6-digit code derived from names.

c: 5-digit zip code.

d: Not all records are expected to match.

Table 4. Characteristics of acute ischemic stroke patients (n = 50,579) cared for by Georgia Coverdell Acute Stroke Registry participating and nonparticipating hospitals, Georgia Hospital Discharge Data, 2006–2009, and Georgia Mortality Data, 2006–2010

Characteristics	Treatment Location			P-Value ^b
	All Hospitals	GCASR Hospitals	Non-GCASR Hospitals ^a	
Age, y, mean (SD)	68.7 (13.9)	68.2 (13.9)	69.3 (13.9)	.12
Sex, n (%)				
Male	24,494 (48.4)	13,948 (49.7)	10,546 (46.9)	<.001
Female	26,085 (51.6)	14,129 (50.3)	11,956 (53.1)	
Race, n (%)				
White	33,619 (66.5)	18,813 (67.0)	14,806 (65.8)	.63
Black	15,695 (31.0)	8,445 (30.1)	7,250 (32.2)	
Other	1,265 (2.5)	819 (2.9)	446 (2.0)	
Primary insurance coverage, n (%)				
Medicare	32,438 (64.1)	17,531 (62.4)	14,907 (66.3)	.31
Medicaid	2,877 (5.7)	1,687 (6.0)	1,190 (5.3)	
Private	10,329 (20.4)	6,088 (21.7)	4,241 (18.8)	
Self-pay	3,607 (7.1)	2,097 (7.5)	1,510 (6.7)	
All others	1,328 (2.6)	674 (2.4)	654 (2.9)	
Length of stay, d, median (interquartile range)	3.0 (2–6)	2.8 (1.3–5.4)	3.2 (1.7–5.6)	.80
Hospital size, n (%)				
<100 beds	70 (53.4)	22 (36.7)	48 (67.6)	<.001
100–249 beds	29 (22.1)	11 (18.3)	18 (25.4)	
250–399 beds	15 (11.5)	12 (20.0)	3 (4.2)	
≥400 beds	17 (13.0)	15 (25.0)	2 (2.8)	
Hospital location, n (%) ^c				
Metropolitan	62 (47.3)	40 (66.7)	22 (31.0)	<.001
Nonmetropolitan	69 (52.7)	20 (33.3)	49 (69.0)	
Calendar year, n (%)				
2006	12,331 (24.4)	4,743 (16.9)	7,588 (33.7)	<.001
2007	12,959 (25.6)	7,175 (25.5)	5,784 (25.7)	
2008	12,849 (25.4)	7,972 (28.4)	4,877 (21.7)	
2009	12,440 (24.6)	8,187 (29.2)	4,253 (18.9)	
No. (%) of deaths				
Discharge	1,940 (3.8)	1,000 (3.6)	940 (4.2)	.08
30 days	4,114 (8.1)	2,105 (7.5)	2,009 (8.9)	<.001
365 days	9,350 (18.5)	4,740 (16.9)	4,610 (20.5)	<.001
End of follow-up	14,699 (29.1)	7,281 (25.9)	7,418 (33.0)	<.001

Abbreviation: GCASR, Georgia Coverdell Acute Stroke Registry; SD, standard deviation.

a: Non-GCASR hospitals are those that never participated in GCASR from 2006 through 2009.

b: χ^2 and Wilcoxon tests were applied for nominal and quantitative variables, respectively.

c: Based on Rural-Urban Commuting Area classification of location to classify hospitals geographically as metropolitan (codes 1–3) or nonmetropolitan (codes >3)⁷.

Table 5. Relative risk for death for Georgians with acute ischemic stroke, Georgia Hospital Discharge Data, 2006–2009, and Georgia Mortality Data, 2006–2010

Characteristic	Hazard Ratio ^a in the First Year Post Stroke Admission	
	Estimate (95% CI)	P-Value ^b
Location of treatment		
Hospital not participating in GCASR	1.14 (1.03–1.26)	.01
Hospital participating in GCASR	1 [Reference]	
Sex		
Male	0.93 (0.89–0.98)	.004
Female	1 [Reference]	
Age group, y		
≥80	5.45 (4.53–6.56)	<.001
65–79	2.18 (1.83–2.62)	<.001
45–64	1.34 (1.14–1.57)	<.001
<45	1 [Reference]	
Race		
Other	1.03 (0.96–1.11)	.36
White	1 [Reference]	
Primary insurance coverage		
Medicaid	1.06 (0.94–1.19)	.35
Private	0.75 (0.67–0.84)	<.001
Self-pay	0.62 (0.51–0.75)	<.001
All others	0.91 (0.80–1.19)	.84
Medicare	1 [Reference]	
Length of stay, d	1.017 (1.013–1.022)	<.001
Hospital size, n (%)		
<100 beds	1.17 (1.02–1.33)	.02
100–249 beds	1.04 (0.92–1.18)	.54
250–399 beds	1.05 (0.91–1.21)	.48
≥400 beds	1 [Reference]	
Hospital location ^c		
Nonmetropolitan	1.11 (1.03–1.21)	.009
Metropolitan	1 [Reference]	
Calendar year		
2006	1.09 (1.02–1.18)	.02
2007	1.09 (1.02–1.17)	.007
2008	1.02 (0.95–1.09)	.64
2009	1 [Reference]	

Abbreviation: CI, confidence interval; GCASR, Georgia Coverdell Acute Stroke Registry.

a: Adjusted for comorbidities.

b: χ^2 and Wilcoxon tests were applied for nominal and quantitative variables, respectively.

c: Based on Rural-Urban Commuting Area classification of location to classify hospitals geographically as metropolitan (codes 1–3) or nonmetropolitan (codes >3).⁷

CHAPTER III

Quality of Care and Its Impact on One Year Mortality: the Georgia Coverdell Acute Stroke Registry

Abstract

Introduction

Although performance measures to monitor the quality of acute stroke care exist, their utility in measuring long-term outcomes is uncertain. This study assessed the 1-year mortality of acute ischemic stroke patients cared for by hospitals participating in the Georgia Coverdell Acute Stroke Registry.

Methods

The 2008-2013 Georgia Coverdell Acute Stroke Registry data were linked with hospital discharge and death data using both hierarchical deterministic and probabilistic linkage procedures. Delivery of care components related to ten nationally-approved performance measures were used to define whether patients received quality care. Defect-free care and composite measure methods were used to measure the quality of care. A generalized estimating equation was applied, accounting for correlation at hospital level and taking hospital as a random variable to assess the effect of quality of care on 1-year mortality.

Results

“Defect-free care” was positively associated with increased mortality; however, it was also associated positively with stroke severity. The composite measure showed that patients who

received the lowest and intermediate quality care, respectively, had a 3.94 (95%CI: 3.27, 4.75; p-value <0.0001) and a 1.38 (95%CI: 1.12, 1.62; p-value=0.002) times higher odds of dying in one year compared to those who got the best quality stroke care.

Conclusion

Data from the Georgia Coverdell Acute Stroke registry suggest that the defect-free care measure is not helpful in assessing the impact of quality improvement activities. However, the composite measure indicated that hospitals should be encouraged to implement quality improvement activities for better long-term stroke patient outcome.

INTRODUCTION

A wealth of scientific evidence shows that improvement in specific elements of clinical stroke care could result in better patient outcomes.³³ The Centers for Disease Control and Prevention (CDC), the American Heart Association, and the Joint Commission have identified ten specific elements of clinical care and developed associated indicators (Table 6) to measure the quality of stroke care.^{32,33} Not every component of stroke care is indicated for all stroke patients; rather, patients receive care based on their specific needs. A patient who received all indicated care components is said to have had a “defect-free care,” an indicator that helps to monitor progress in the quality of stroke care delivery.

The Georgia Coverdell Acute Stroke Registry (GCASR) was established by the Georgia Department of Public Health, in collaboration with its partners and funded by CDC, to measure, monitor, and improve the quality of acute stroke care across the state. Hospitals participating in GCASR have shown significant improvement in the process of stroke patient care and delivery of defect-free care.^{34,36} Nevertheless, improvement in the process of care delivery may not necessarily translate into improvement in patient outcomes.²⁴⁻²⁶ Hence, the objective of this study was to assess whether quality improvement as measured by defect-free care or a composite measure is associated with improved short- and long-term outcomes among acute ischemic stroke patients.

METHODS

Data Sources and Linkage

This is a retrospective cohort study of acute ischemic stroke patients cared for by GCASR-participating hospitals during 2008-2013. We used three data sources – the GCASR data, the Georgia Discharge Data System (GDDS) and the Georgia death data. We linked the GCASR and GDDS data using a hierarchical deterministic linkage procedure (sensitivity 87% and positive predictive value 96%); the output was then linked with the death data applying a probabilistic linkage approach (sensitivity 92% and specificity 100%). The probabilistic linkage procedure and its yield is described previously⁶⁸, and details on the deterministic linkage procedure are provided as Annex. The Fine-Grained Record Integration and Linkage software program version 2.1.5 was used to link the three data sources were linked stepwise using.⁴²

Patients from the stroke registry with clinical diagnosis of acute ischemic stroke in 2008–2013 were included in this study. We had 45,727 records with a clinical diagnosis of acute ischemic stroke in the initial GCASR data list. Of these, 41,216 were linked with GDDS data but only 39,331 had the data element critical for linking with the death data. Excluding the readmissions, we had 36,043 subjects eligible for follow-up, and 35,028 were eligible for, at least, one evidence-based stroke care component. We excluded from the analysis patients with undocumented time of symptom onset because 59% of the observations have missing value (Figure 1).

Defect-free Care Measure

Patients were classified as having had a defect-free care if they received all elements for which they were eligible as specified by the ten performance measures (Table 6). Defect-free care does not take into account the number of care components patients are eligible to receive. Thus, a patient who is eligible for three care components and received all is declared as having had a defect-free care while a patient who received seven out of eight indicated care components is identified as not having had a defect-free care.

Composite Measure

A composite measure, taking the proportion of indicated care components a patient received, is an alternative measure of quality of care.^{47,69} However, it doesn't fully account for the number of indicated care components because delivery of eight out of eight would have the same composite measure of 100% as providing three out of three. Thus, we weighted the composite measure by the natural logarithm of the total number of indicated care components. The care requiring eight elements will have a higher weight [$\ln(8)=2.0794$] than the one with three indicated care components [$\ln(3)=1.0986$]. Patients were grouped in tertiles based on their weighted composite measures. Those in the 1st tertile with the lowest weighted composite measure were considered to have had, relatively, the lowest quality of care; those in the 2nd tertile represented an intermediate and patients in the 3rd tertile represented the best quality of stroke care.

Statistical Analyses

All analyses were done using SAS® version 9.3 (SAS Institute, Inc., Cary, NC). Quality of stroke care as measured by defect-free care or the composite indicator was the main predictor of outcome. Death from any cause within 365 days from index admission and ambulatory status at discharge were the outcomes of interest. We classified ambulatory status at discharge into two groups: unable to walk, and walking with or without assistance from another person. Those who were not ambulating independently before the stroke event were excluded from the analysis.

Patient's characteristics such as age, gender, race and insurance status, National Institute of Health (NIH) stroke scale score, presence of persistent atrial fibrillation or flutter, previous medical and medication history and nothing per mouth status; event-related characteristics such as symptom onset to hospital arrival time, day, time and year of admission; and hospital features including number of beds and location were considered as covariates in the analysis. Based on their distribution on the basis of number of beds, hospitals were classified as small (<100 beds), medium-small (100–249 beds), medium-large (250–399 beds) and large hospitals (≥ 400 beds). We used the Rural-Urban Commuting Area classification (version 2.0) of location to classify hospitals geographically into metropolitan (codes 1–3) and nonmetropolitan (codes >3).⁴³ We assessed patient, hospital and event related characteristics descriptively and tested for differences between patients who did and did not receive defect-free care using χ^2 tests for nominal variables and Wilcoxon tests for quantitative variables.

Data elements included in the multivariable analyses had missing values in less than 5% of the observations except for NIH stroke scale which has missing values for 29% of the observations, respectively. Therefore, we performed multiple imputation with 20 replications

assuming a general missing pattern and missing at random on data elements included in the analysis.⁷⁰ We applied generalized estimating equations (GLIMMIX procedure) to assess the outcomes controlling for in-hospital correlation and considering hospital as a random variable.

RESULTS

Among the 14,246 acute ischemic stroke patients included in the study, 51.3% were female, 61.8% were White, and the median age was 69 years (IQR: 58, 80). The three most common comorbidities were hypertension (82.4%), dyslipidemia (41.1%) and diabetes mellitus (34.5%). Based on the ten performance measures, 69.1% received defect-free care and on aggregate patients received 92.8% of the indicated care components. Patients who received defect-free care had more severe stroke than their counterparts; a relatively higher proportion of them were also non-ambulating at discharge and died within one year of the incident (Table 7).

Patients with more number of indicated care components were less likely to receive defect-free care (Figure 2) than those with relatively fewer indicated elements of stroke care. Moreover, stroke was more severe among patients with fewer indicated care components (Figure 3). Patients with three or fewer indicated care components had a 72.9% 1-year mortality while those with more than three had a 12.4% 1-year mortality.

The 1-year mortality among patients with a missing value in a predictor variable was 19.1% compared to the 19.7% among those with complete data. On multivariate analyses of the imputed data, patients who did not receive defect-free care had a 0.87 (95%CI: 0.75, 1.00; p-value=0.05) lower odds of dying in one year compared to those who received defect-free care. Moreover, they also had a 0.58 (95%CI: 0.48, 0.67; p-value<0.0001) lower odds of not

ambulating at discharge. Nonetheless, when quality of stroke care was measured by the composite indicator, those who received the lowest and intermediate quality of care had higher odds (OR=3.94; 95%CI: 3.27, 4.75; p-value <0.0001 and OR=1.35; 95%CI: 1.12, 1.62; p-value=0.002, respectively) of dying within one year compared to those who received the best quality stroke care. Furthermore, patients with the lowest and intermediate quality care had statistically significant 5.7 times (95%CI: 4.59, 7.06; p-value<0.0001) and 3.08 (95%CI: 2.53, 3.75; p-value<0.0001) greater odds, respectively, of not ambulating at discharge compared to their counterparts. (Table 8). Similar results were also documented on complete data analysis.

DISCUSSION

The result of this study shows that acute ischemic stroke patients who received a quality care had a better long-term outcome. The odds for dying within one year increased progressively as the quality of care patients received diminished. Similarly, a statistically significant positive association was documented between the quality of stroke care and patients' ambulatory status at discharge.

Contrary to what is expected, patients who did not receive better care, as measured by defect-free care, appeared to have better outcomes. They had a 13% and a 42% lower odds of dying in the first year and non-ambulating at discharge, respectively, compared to those who received defect-free care. Our analysis further revealed that patients with more severe stroke were eligible to receive fewer number of care components and were more likely to have defect-free care. Although we adjusted for measures of disease acuity, including the NIH stroke scale score, we cannot vouch that severity is captured fully by the score.

Compared to the all-or-none scoring of defect-free care, the composite measure captured intermediate level care quality and gave credit for delivery of some, not necessarily all, of the indicated care processes. It gave equal weight to each care component and presented quality of care on a continuous scale rather than as a binary outcome. The impact of each care element on patient outcome, however, may be different and this may require assigning different weights.

This study has some methodological limitations. Fourteen percent of the initial study subject were excluded because they did not match records from the hospital discharge data. Obviously this could introduce bias, namely a non-differential bias because record matching was not related to the quality of care patients received. Patient without documented symptom onset time were also excluded, and we imputed for missing values, mainly for NIH stroke scale score, for a third of the study subjects. This may introduce bias as well; however, the 1-year mortality weren't different between patients with and without complete data. Despite these limitations, our findings were also similar in both the complete and imputed data analyses, indicating that the bias would only be minimal.

Measuring quality of care is an arduous exercise and requires rigorous examination of what each measure entails. It involves identifying care components that would have effect on patient outcome, defining the subset of patient groups who would be eligible, establishing procedures for delivery and documentation of the care component and determining whether an eligible patient received the care indicated. It is possible that errors could be introduced at any step of assessing the quality of care delivery. The error gets compounded when measures of several quality of care components are aggregated in an all-or-none fashion as in defect-free care. The composite measure, on the other hand, was not influenced by the number of care

components indicated for a patient. Error in measurement of one care component could affect partly the aggregate measure of quality of care. Thus, defect-free care, though a stringent aggregate indicator for monitoring and improving the process of care delivery, is not the ideal quality measure when the impact of quality improvement initiatives in stroke care is evaluated.

Although each component of stroke care is backed by scientific evidences,³³ it is important to evaluate their effectiveness in the aggregate, in the context of a quality improvement initiative. To the best of our knowledge, no study has examined the long-term effects of hospital-based quality improvement initiative in stroke care. This study assessed both short and long-term outcomes and showed that patients who received better care had a lower risk of death, a finding which could expand quality improvement activities across hospitals caring for stroke patients.

Conclusion

Quality improvement initiatives improve not only the process of care delivery but also patient outcome. Hospitals should be encouraged to undertake quality improvement activities to measure and monitor the nationally recommended performance indicators in order to improve the quality of their stroke patient care.

Table 6. Performance measures endorsed by the CDC, the American Heart Association/American Stroke Association and the Joint Commission

Performance measures
Venous thromboembolism prophylaxis
Administration of antithrombotic medication within 48 hours
Anticoagulant medication for patients with atrial fibrillation
Administration of tissue plasminogen activator (tPA)
Dysphagia screening
Antithrombotic medication at discharge
Prescription of lipid lowering medication
Stroke education
Smoking cessation counseling or treatment
Rehabilitation assessment

Source: *MMWR Morb Mortal Wkly Rep.* 2011;60(7):206-10.

Table 7. Characteristics of acute ischemic patients by defect-free care status, Georgia Coverdell Acute Stroke Registry, 2008–2013

Characteristics	Total	Patient Did Not Receive DFC ^a	Patient Received DFC ^a	P-value ^b
Age, median (IQR)	69 (58, 80)	68 (57, 79)	69 (58, 80)	<.0001
Female, n(%)	7,309 (51.3)	2,291 (52.1)	5,018 (51.0)	0.20
Whites, n(%)	8,808 (61.8)	2,828 (64.30)	5,980 (60.7)	<.0001
Medicare health insurance coverage, n(%)	8,497 (59.7)	2,552 (58.1)	5,945 (60.4)	0.01
NIH stroke scale score (unit), median (IQR)	6 (2, 13)	4 (1, 9)	6 (2, 14)	<.0001
Atrial fibrillation/flutter, n(%)	2,936 (20.6)	796 (18.1)	2,140 (21.7)	<.0001
Nothing per mouth, n(%)	1,323 (9.3)	232 (5.3)	1,091 (11.1)	<.0001
Last known well to hospital arrival time (minutes), median(IQR)	183 (69, 460)	158 (66, 399)	195 (71, 480)	<.0001
Hospital bed size, n(%)				
<100 beds	483 (3.4)	307 (7.0)	176 (1.8)	<.0001
100–249 beds	2,378 (16.7)	884(20.1)	1,494 (15.2)	
250–399 beds	3,424 (24.0)	1,005 (22.9)	2,419 (24.6)	
>=400 beds	7,961 (55.9)	2,200 (50.0)	5,761 (58.5)	
Day of the week, ^c n(%)				
Week day	10,018 (71.7)	3,191 (72.6)	7,097 (72.1)	0.51
Weekend	3,958 (28.3)	1,205 (27.4)	2,753 (27.9)	
Hour of the day, ^c n(%)				
Night	5,217 (36.6)	1,600 (36.4)	3,617 (36.7)	0.71
Day	9,029 (63.4)	2,796 (63.6)	6,233 (63.3)	
Calendar year, n(%)				
2008	1,419 (10.0)	911 (20.7)	508 (5.2)	<.0001
2009	1,656 (11.6)	873 (19.9)	783 (7.9)	
2010	2,231 (15.7)	600 (13.6)	1,631 (16.6)	
2011	2,617 (18.4)	651 (14.8)	1,966 (20.0)	
2012	3,088 (21.7)	702 (16.0)	2,386 (24.2)	
2013	3,235 (22.7)	659 (15.0)	2,576 (26.2)	
Outcome, n(%)				
Death in 1-Year	2,775 (19.5)	672 (15.3)	2,103 (21.4)	<.0001
Not ambulating at discharge ^d	1,594 (14.0)	303 (8.5)	1,291 (16.5)	<.0001

Note:- IQR = Interquartile range; DFC = Defect-free care

a: Defect-free care: delivery of care meeting all quality indicators for which a patient is eligible

b: chi-square and Wilcoxon tests were applied for nominal and quantitative variables, respectively.

c: refers to the admission day and time

d: among patients who were ambulating prior to the stroke incident

Table 8. Relative risk of 1-year mortality and non-ambulating at discharge among acute ischemic stroke patients by quality of care, Georgia Coverdell Acute Stroke Registry 2008-2013.

Performance measure	Complete Data				Imputed Data			
	Death in one year post incident		Not Ambulating at Discharge ^a		Death in one year post incident		Not Ambulating at Discharge ^a	
	Odds Ratio (95% CI)	P-value	Odds Ratio (95% CI)	P-value	Odds Ratio (95% CI)	P-value	Odds Ratio (95% CI)	P-value
Received defect-free care ^b								
No	0.84 (0.69, 1.02)	0.073	0.67 (0.54, 0.82)	0.0003	0.87 (0.75, 1.00)	0.05	0.58 (0.48, 0.67)	<0.0001
Yes	Referent		Referent		Referent		Referent	
Weighted Composite Index ^c								
1 st Tertile	4.10 (3.27, 5.13)	<0.0001	6.64 (5.09, 8.66)	<0.0001	3.94 (3.27, 4.75)	<0.0001	5.70 (4.59, 7.06)	<0.0001
2 nd Tertile	1.28 (1.02, 1.60)		3.06 (2.41, 3.89)		1.35 (1.12, 1.62)	0.002	3.08 (2.53, 3.75)	<0.0001
3 rd Tertile	Referent		Referent		Referent		Referent	

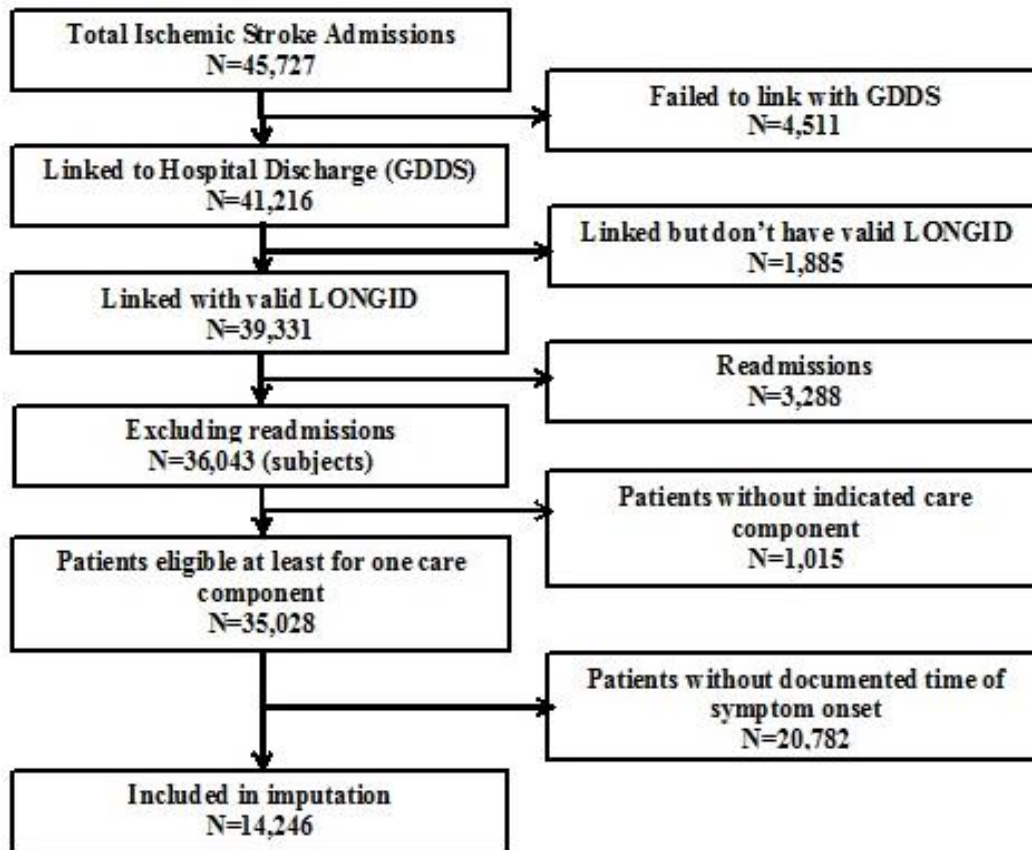
Note:- the estimates are adjusted for age, gender, race and insurance status, National Institute of Health stroke scale score, presence of persistent atrial fibrillation or flutter, previous medical and medication history and nothing per mouth status, symptom onset to hospital arrival time, time, day year of admission, hospital number of beds and location.

a: among patients who were ambulating on prior to the stroke incident

b: a patient who received all the indicated care components related to the ten performance measures is labelled to have had a defect-free care

c: proportion of performance measures weighted by natural logarithm of the total number of indicated care components; the quality of care improves going from the first to the third tertile

Figure 1. Flow diagram for patients included in the analysis



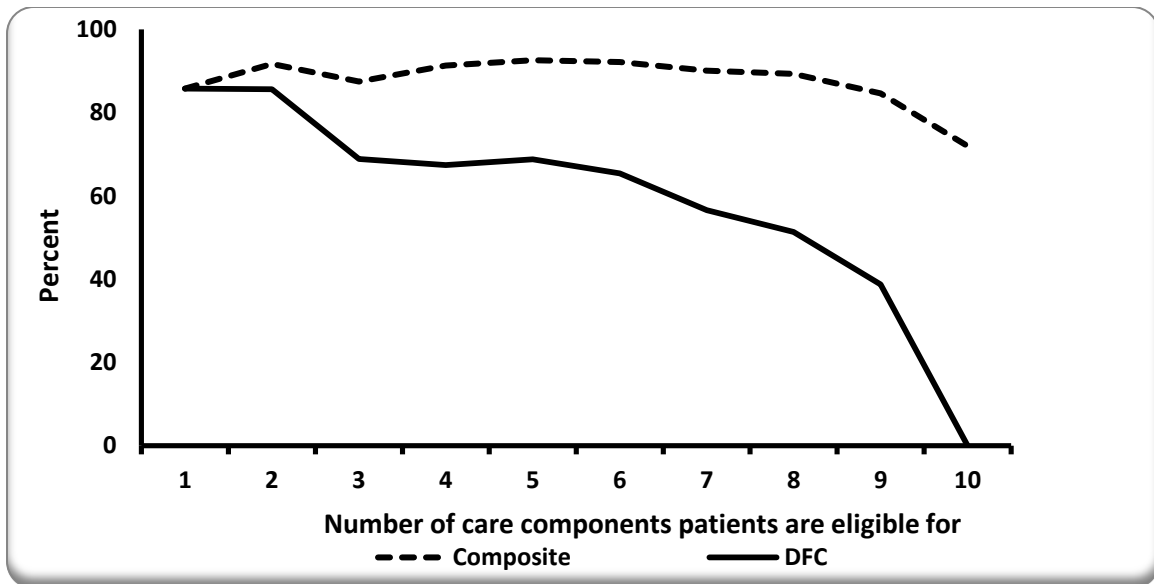


Figure 2. Defect-free care and average composite measure by the number of performance measure acute ischemic patients were eligible for, Georgia Coverdell Acute Stroke Registry, 2008-2013

(DFC (defect-free care): when a patient received all the care components related to the ten performance measures that are indicated)

Composite: the percentage of indicated performance measures a patient received)

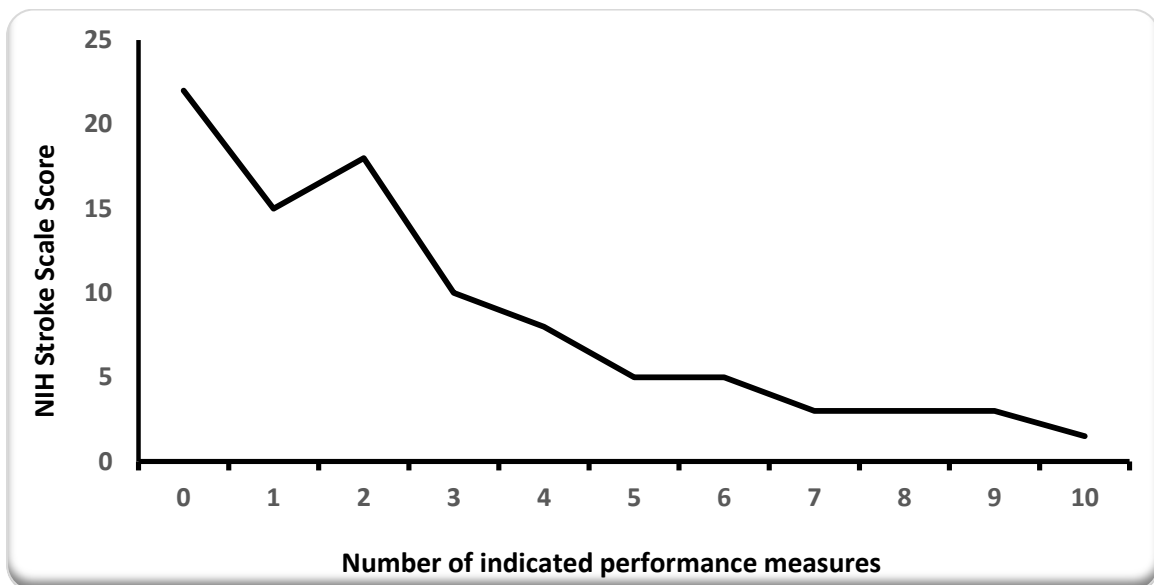


Figure 3. Median National Institute of Health stroke scale score by the number of performance measure acute ischemic patients were eligible for, Georgia Coverdell Acute Stroke Registry, 2008-2013

CHAPTER IV

The Impact of Intravenous Alteplase on Long-term Patient Survival: the Georgia Coverdell Acute Stroke Registry's Experience

Abstract

Introduction

Intravenous alteplase reduces disability and improves functionality among acute ischemic stroke patients. Two decades after its approval, only a small fraction of patients get the treatment, and demonstrating its impact on mortality may make a strong case for its wider use. This study assessed the impact of thrombolytic treatment by alteplase on 1-year mortality and readmission among acute ischemic stroke patients.

Method

The 2008-2013 Georgia Coverdell Acute Stroke Registry data were linked with the 2008-2013 hospital discharge and the 2008-2014 death data in Georgia. Multiple imputation was applied; a propensity score measuring the probability of receiving intravenous alteplase was calculated and used for matching. A conditional logistic regression was applied to compare 1-year mortality and readmission among propensity score matched pairs.

Results

Overall, 20.3% of 9,620 acute ischemic stroke patients died and 22.4% were readmitted in one year. The multivariable regression result showed that patients who did not receive IV alteplase had a 1.49 (95%CI: 1.09-2.04; p-value=0.01) times higher odds of dying at one year

than those who were treated with the thrombolytic agent. Among patients discharged home, no statistically significant difference was documented in the odds of being readmitted at least once within 365 days post-stroke discharge.

Discussion and Conclusion

The benefits of intravenous alteplase are not limited to improvement in function or absence of disability but also in reduction of mortality. The results of this study suggests that patients who are identified as eligible for intravenous alteplase need to be offered the treatment.

INTRODUCTION

Intravenous alteplase was approved in 1996 by FDA as a thrombolytic agent in ischemic stroke because patients who received the treatment are 30% more likely to have minimal or no disability at three month after the index incident⁷¹ and one year after the index incident.⁷² Twenty years later, fewer than 10% of ischemic stroke patients receive the treatment.^{73,74} Delay in stroke identification, lack of swift transport to stroke ready facilities, contraindications and warning symptoms, and indecision to provide intravenous (IV) alteplase by healthcare providers,^{75,76} may be associated with low rates of alteplase use.

Demonstration of IV alteplase's impact on long-term mortality rather than on disability could make a strong case for its wider use. To date, the few studies designed to assess patient outcome using mortality have not shown positive results, possibly because of shorter duration of follow-ups, differential effect of IV alteplase based on stroke severity, and small sample size.^{72,77-79} Stroke registries help to monitor and measure patient outcomes in the long-term and provide data to support the needed research.⁸⁰ This study is conducted to evaluate the impact of receiving intravenous thrombolytic treatment on 1-year mortality of stroke patients cared for by hospitals participating in the Georgia Coverdell Acute Stroke Registry.

METHODS

We conducted a passive follow-up of acute ischemic stroke patients cared for by hospitals participating in the Georgia Coverdell Acute Stroke Registry (GCASR). The Georgia Coverdell Acute Stroke Registry is part of the National Paul Coverdell Acute Stroke Program and is designed to monitor the quality of stroke care in the state.³² The registry has the goal of

reducing stroke disability, premature mortality and preventing recurrent stroke through improvement in quality of stroke care in collaboration with the participating hospitals and other stakeholders.

Data Sources and data linkage

We used the 2008-2013 GCASR data, the 2008-2013 Georgia Discharge Data System (GDDS) and the 2008-2014 Georgia death data for this study. The GDDS has information on patients discharged from non-federal acute care hospitals in Georgia. The death data are collected from death certificates and provide information on deaths of Georgians including those who passed away in other states. The three data sources were linked stepwise using the Fine-Grained Record Integration and Linkage software program version 2.1.5.⁴² First, we linked the GCASR data with GDDS data using a hierarchical deterministic procedure; the output was, subsequently, linked with the death data using a probabilistic data linkage approach. We used hospital code, admission and discharge date, age, race and gender for matching the GCASR data with GDDS data. Additional information on residence (ZIP code and county) and a 15 digit alphanumeric code – composed of the first two letters of the first name, the first and last two letters of last name, birthdate and gender – were added for the probabilistic linkage.

Similar to a previous study, in which the probabilistic linkage between hospital discharge and death data was seen to have a very good accuracy with 92% sensitivity and 100% specificity,⁶⁸ the deterministic linkage in this study had a sensitivity of 87% and positive predictive value of 96% (details provided as Annex). There were 45,727 records with a clinical diagnosis of acute ischemic stroke in the initial GCASR data list. Of these, 41,216 were linked with GDDS data but only 39,331 had LONGID, the data element critical for linking with the

death data and for determining readmissions from index admission. After excluding the readmissions, 36,043 subjects were eligible for follow-up (Figure 4).

Inclusion and Exclusion Criteria

In this study, we included only subjects who were eligible for IV alteplase administration. Based on AHA's guidelines for the early management of patients with acute ischemic stroke,⁸¹ patients with contraindications and warning symptoms and those with spontaneous stroke symptom recovery or a National Institute of Health (NIH) stroke scale score of zero were considered ineligible for IV alteplase. We excluded from analysis patients with in-hospital stroke, symptom onset (last known to be well) to hospital arrival time greater than 270 minutes or no symptom onset time documented and patients from hospitals with no IV alteplase treated patients during the study period.

Statistical Analysis

The main outcome of interest was death from any cause within 365 days after index patients' admission. Readmission for any cause within 365 days post discharge among patients discharged home was also assessed as a secondary outcome. Treatment with IV alteplase documented in the registry was the main predictor of outcome.

Data elements included in the analyses had missing values in less than 5% of the observations except for NIH stroke scale which had 29% missing values. Altogether, 38% of the observations had missing value at least for one variable. Therefore, we performed multiple imputation on 9,620 observations assuming a general missing pattern and missing at random with twenty replications on variables considered to have relation with receiving IV alteplase and

patient's outcome.⁷⁰ To assess for bias from imputation, we analyzed the data with complete information as well.

A propensity score measuring the probability of receiving IV alteplase was calculated using variables that could be related to the decision of administering thrombolytic. Age, gender, race, Medicare as major source of health insurance, transport to hospital by EMS, last known well to hospital arrival time, history of other illnesses and medication, severity of patient condition as documented by NIH stroke scale score and nothing per mouth status, hospital bed size, hour, day and year of admission were treated as predictors. Hospital bed size and NIH Stroke Scale score were categorized based on their distribution; hospital bed size was classified as small (<100 beds), medium-small (101-249 beds), medium-large (250-400 beds) and large (>400 beds) while the NIH Stroke Score was classified in quartiles (0-4, 5-8, 9-14, and greater than 14). Hospitals were classified geographically as metropolitan (codes 1-3) and non-metropolitan (codes >3) based on the Rural-Urban Commuting Area classification (version2.0) of location.⁴³

We used the propensity score for variable reduction and matching.⁸² Patients treated with IV alteplase were matched one-to one with those eligible but didn't receive the treatment using a SAS macro program.⁸³ Alteplase treated patients were first matched to controls on 8 digits of the propensity score. Those that did not match were then matched to controls on 7 digits of the score, and we continued the matching down to a 1-digit match. The average difference in propensity score between the matched pairs was less than 0.001.

We compared the characteristics of IV alteplase treated and non-treated patients, among those eligible for the thrombolytic medication and with complete information, using chi-square test for categorical variables and Wilcoxon test for continuous variables. We compared outcomes, on imputed data, among propensity score matched pairs using conditional logistic regression. The analyses were done using the SAS® statistical software version 9.3 (SAS Institute, Inc.).

RESULTS

The final analytical dataset had 9,620 patients from 48 hospitals with a median age of 68 years (IQR: 57, 80 years). More than half (52%) were female, 60% were white, 59% had Medicare as their main source of health insurance coverage, and 25.8% received IV alteplase. The average overall mortality rates documented were 4.6% at 7 days, 10.4% at 30 days, 13.5% at 90 days and 20.3% at one year. Moreover, 22.4% of the patients were readmitted within one year post discharge. Based on information from patients with complete data (n=2,925), patients treated with IV alteplase had statistically significantly different features including age, health insurance coverage, means of transport to hospital, NIH stroke scale score, NPO status and medication intake prior to admission compared to those who were eligible but didn't receive the treatment (Table 9).

The one year mortality among patients with a missing value in a predictor variable was 20.5% compared to the 22.3% among those with complete data. The aggregate conditional logistic regression result from imputed data showed that patients who did not receive IV alteplase had a 1.49 (95%CI: 1.09-2.04; p-value=0.01) times higher odds of dying at one year than those who were treated with the thrombolytic agent (Table 10). The lowest and highest odds

ratios observed in the twenty replicates were 1.22 and 1.70, respectively. Moreover, the analysis on complete records (n=348 pairs) showed a result in similar direction albeit statistically not as significant (p-value=0.37) as the one on imputed data (Table 10). Among patients discharged home, no statistically significant difference (OR=0.90, 95%CI: 0.59, 1.39, p-value=0.24) was documented in the odds of being readmitted at least once within 365 days post discharge (Table 2).

DISCUSSION

Acute ischemic stroke patients who were treated with intravenous thrombolysis had a better odds of survival at one year post discharge. Those who were eligible but didn't receive intravenous alteplase had a 49% higher odds of dying at one year than those who received the thrombolytic agent. The data, however, didn't show evidence that intravenous thrombolysis reduces 1-year readmission among patients discharged home.

Prior studies with randomized design haven't shown a statistically significant reduction of 1-year mortality for patients treated IV alteplase.^{72,77-79} The observed difference might be due to differences in characteristics of study populations. The NINDS study⁷² applied exclusion criteria similar to those used in this study, but it included only patients who could be treated within 3 hours of symptom onset. The third International Stroke Trial (IST) study,⁷⁷ on the other hand, included patients who neither had a clear indication nor contraindication for IV alteplase and who could be treated within 6 hours of symptom onset.

Administration of IV alteplase has its own risk for complication such as bleeding and is not indicated for all patients who present with acute ischemic stroke. In this study, we considered

only patients who do not have a condition that may preclude the use of IV alteplase. In a similar observational study,⁸⁰ where only eligible patients as defined by national guidelines were considered, Schmitz et al. reported a similar finding (Hazard Ratio = 1.52; 95% confidence interval, 1.14–2.04) based on the Danish Stroke Registry.

Some shortcomings are worth considering in the interpretation of the result of this study. One, aside from the clinical diagnosis, no imaging information was available to differentiate the type and extent of ischemic insult that may affect patient outcome.⁸⁴ Two, the data linkage left out 14% unmatched patient records and could potentially introduce bias. Three, we applied multiple imputation to get accurate estimates that are generalizable to the study population. Patients with missing data had a 1-year mortality (20.5%) comparable to those with complete data (21.3%). Thus, it is reasonable to assume that missingness were at random. Although bias could potentially be introduced, analysis of complete data produced results similar to the ones generated from imputed data. Estimates for each replicate datasets from the multiple imputation also indicated an association between IV alteplase treatment and 1-yr mortality in the same direction.

This study adds more positive results to the existing literature on the impact of IV alteplase particularly in the context of its effectiveness and hospitals' effort to improve the overall quality of acute stroke care. The results would help healthcare providers make their decision promptly and save valuable time in the care of stroke patients.

Conclusions

The results of this study suggest that patients who are eligible be determined as swiftly as possible and those identified as eligible receive the treatment. Besides improvement in function and absence of disability, intravenous alteplase administration is associated with reduction in long-term mortality.

Table 9. Characteristics of acute ischemic stroke patients eligible for IV alteplase and with complete information (n=2925), Georgia Coverdell Acute Stroke Registry, 2008-2013.

Characteristics	Treated with IV ALTEPLASE (n=1,937)	Not Treated with IV ALTEPLASE (n=988)	p-value ^a
Age, years, median(IQR)	68 (57, 79)	71 (61, 81.5)	0.0005
Female, n(%)	990 (51.1)	512 (51.8)	0.72
Whites, n(%)	1,169 (60.4)	632 (64.0)	0.06
Medicare as the principal health insurance coverage, n(%)	1,108 (57.2)	653 (66.1)	<0.0001
Brought by EMS, n(%)	1,660 (85.7)	683 (69.1)	<0.0001
NIH Stroke scale score, unit, median(IQR)	11 (7, 18)	5 (3, 12)	<0.0001
Persistent or Paroxysmal Atrial Fibrillation/Flutter, n(%)	472 (24.4)	231 (23.4)	0.55
Nothing per mouth status	317 (16.4)	100 (10.1)	<0.0001
Medication prior to admission, n(%)			
Antihypertensive	1,356 (70.0)	766 (77.5)	<0.0001
Lipid lowering drug	760 (39.2)	448 (45.3)	0.002
Medical history of, n(%)			
Dyslipidemia	751 (38.8)	436 (44.1)	0.01
Diabetes mellitus	521 (26.9)	339 (34.3)	<0.0001
Hypertension	1,567 (80.9)	835 (84.5)	0.02
Coronary artery disease (MI)	463 (23.9)	258 (26.1)	0.19
Heart failure	207 (10.7)	113 (11.4)	0.54
Atrial fibrillation/flutter	374 (19.3)	186 (18.8)	0.75
Smoking	451 (23.3)	200 (20.2)	0.06
Last known well to hospital arrival time, minutes, median(IQR)	60 (40, 88)	191 (120, 230)	<0.0001
Hospital bed size, n(%)			
<100 beds	30 (1.5)	31 (3.1)	0.0009
100–249 beds	256 (13.2)	163 (16.5)	
250–399 beds	422 (21.8)	183 (18.5)	
≥400 beds	1,229 (63.4)	611 (61.8)	
Admitted on, n(%)			
Weekend	540 (27.9)	282 (28.5)	0.71
Day time	1,259 (65.0)	614 (62.1)	0.13
Calendar Year, n(%)			
2008	142 (7.3)	197 (19.9)	<0.0001
2009	198 (10.2)	180 (18.2)	
2010	306 (15.8)	147 (14.9)	
2011	343 (17.7)	140 (14.2)	
2012	441 (22.8)	178 (18.0)	
2013	507 (26.2)	146 (14.8)	
One year Outcome, n(%)			
Mortality	424 (21.9)	227 (23.0)	0.50
Readmission	463 (23.9)	233 (23.6)	0.85

Abbreviation: IQR, Interquartile range

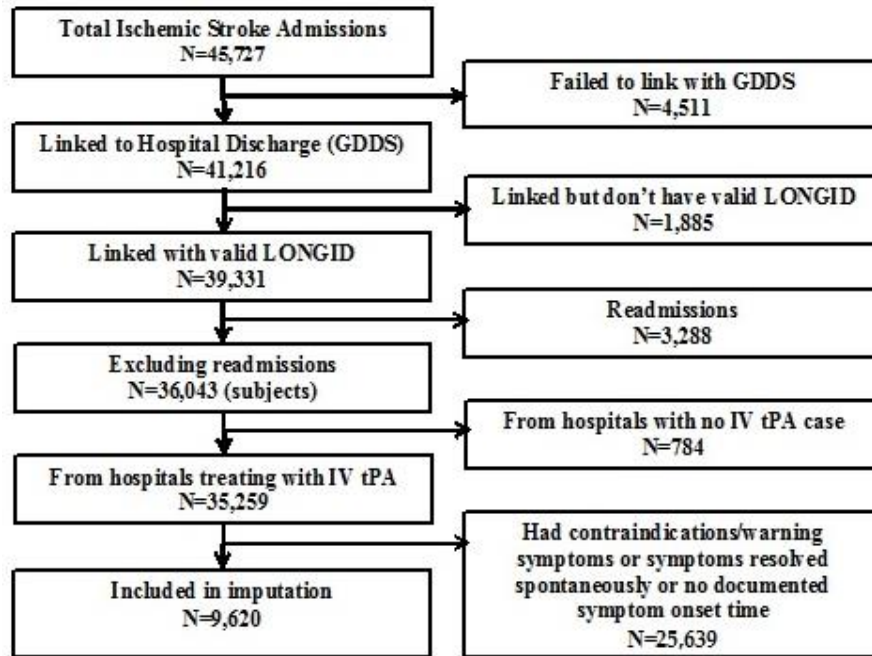
^a χ^2 and Wilcoxon tests were applied for nominal and quantitative variables, respectively.

Table 10. Relative risk of 1-year mortality and readmission by intravenous alteplase treatment status, Georgia Coverdell Acute Stroke Registry 2008-2013.

Outcome	Complete Data		Imputed Data	
	Odds Ratio (95%CL)	p-value	Odds Ratio (95%CL)	p-value
1-year Mortality				
Didn't receive IV alteplase	1.12 (0.83,1.67)	0.37	1.49 (1.09, 2.04)	0.01
Received IV alteplase	Referent		Referent	
1-year Readmission				
Didn't receive IV alteplase	0.81 (0.48, 1.38)	0.44	0.90 (0.59, 1.39)	0.64
Received IV alteplase	Referent		Referent	

N.B.:- CL=Confidence limit; IV=Intravenous
 Alteplase treated patients were matched one-to-one with eligible non-treated patients on probability of receiving IV alteplase (propensity score), and conditional logistic regression applied

Figure 4. Flow diagram for patients included in the analysis



CHAPTER V

SUMMARY

The three studies demonstrated that registry-based quality improvement is an effective strategy to improve the quality of stroke care. Patients treated at hospitals participating in the Georgia Coverdell Acute Stroke Registry had a better survival rate than those cared for by hospitals not participating in the registry. Among patients treated at GCASR participating hospitals, delivery of a better quality care was associated with a lower 1-year mortality. Moreover, acute ischemic stroke patients who received intravenous alteplase had a lower mortality rate compared to those who were eligible but didn't receive the treatment.

In the past two decades, the management of acute stroke has been continuously changing. The approval for clot busting drug use in ischemic stroke has revolutionized the treatment paradigm from simple palliative care to prevention of death and disability, and control of risk factors. But with each scientific discovery to ameliorate the untoward effects of stroke incident comes the need for making the new treatment available for patients. Currently, there is a gap between what is known as the best care and what is actually being practiced by healthcare providers. The national institute of neurological disorders and stroke, in fact, has identified translation of scientific discovery as a priority area for its action.

Researchers have highlighted that the strategy of knowledge translation has evolved from a simple passive diffusion where published scientific discoveries are expected to be read, understood and assimilated in routine care delivery by practitioners to quality improvement and system change.⁹ In line with this, GCASR, funded by the CDC, adopted the strategy of monitoring the quality of stroke care using performance measures. Hospitals modified care

processes in their effort to raise their performance measures, and thus improving the quality of care stroke patients receive. Performance measures have their own short comings, even when there is agreement on what to measure, in terms of complexity of algorithm, clarity of definition of data elements feeding to the performance measure, data quality and validity of the measure. Nevertheless, they indicate, on average, the quality of care delivered to stroke patients by a healthcare facility.

Performance measures are process indicators and are meant to display quality of service at hospital level. They serve for monitoring quality improvement efforts and the progress achieved in improving the process of care delivery. In these studies, however, they are also used to measure quality of care at a patient level to assess patient outcome. Understandably, the results indicate that process indicators may not necessarily capture the essence of quality of care adequately to serve as a proxy measure in analyzing impact. Therefore, it is imperative in any evaluation of impact of quality of care, appropriate measures are used to capture quality in the first place.

Quality is an abstract concept which cannot be measured directly. The Institute of Medicine outlines specific components that constitute quality in a clinical care: safety, effectiveness, patient-centeredness, timeliness, efficiency, and equitability.⁸⁵ It is an arduous effort to develop an indicator that encompasses all these aspects of quality in one. Nevertheless, there are statistical techniques that would serve to define abstract constructs such as “*quality*” using indicator variables. Therefore, it will be a worthwhile effort to develop latent models using either performance measures or any additional patient level information to classify whether a

patient, in fact, has received a quality care rather than just adding each performance measure or apply an all-or-none rule to measure quality.

Time is a critical element in the management of stroke patients, and emergency medical services play a significant role in identifying and transporting stroke patients to stroke ready hospitals. Moreover, how they handle patients with a presumptive diagnosis of stroke has its bearing on the subsequent in-hospital care and on patients' outcome. There are care processes that need to be aligned with evidence-based best practices. On the other hand, stroke is an overwhelming experience both for patients and their caregivers. Once patients are discharged, they require regular follow-ups, either for rehabilitation services or simply to ensure that they adhere to the guideline they receive at discharge. Efforts are being made to develop evidence based clinical guidelines on the post-hospital care of stroke patients, and there will be a room for quality improvement as a strategy to bring those best practices to patient fruition. Thus, it will be necessary to evaluate effectiveness of quality improvement efforts both in the pre-hospital and post-hospital settings.

Quality improvement in stroke care is not one single intervention; rather it is a multifaceted strategy and comprises of several activities each one with its own effectiveness, fidelity in implementation, efficiency, reach and impact on patient outcome. It is critical, therefore, to identify elements that are core to the strategy before contemplating to scale-up quality improvement to other stroke care facilities or disease conditions. Evaluating a quality improvement initiative also requires determining which aspect, which system change, or process or outcome should be examined. Given the readily availability of data sources, end results such as mortality, disability and readmission give the opportunity to capture the ultimate impact of

quality improvement program without discerning how much is contributed by which component. These studies, therefore, serve as examples and could be replicated for similar initiatives around any disease condition.

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ANNEX

Linkage Between The Georgia Coverdell Acute Stroke Registry And The Georgia Discharge Data System

The Georgia Coverdell Acute Stroke Registry (GCASR) data has only non-specific information including age, sex, race, date of admission and discharge, and facility code. It has about 200 variables and more than 10,000 observations per year. It is assumed that the non-specific information listed would be sufficient to get a reasonably acceptable yield when the registry is linked to hospital discharge (GDDS) data.

The hospital discharge data are collected for administrative purpose on all patients who are hospitalized in non-federal acute care or critical access hospitals in the state of Georgia. The data set has about 75 variables and more than a million observations per year. Among the hospital discharges, more than fifty thousand are for adults 18 years and older with an ICD 9 code of stroke (430-438) in one of the ten diagnosis fields.

The GCASR and GDDS data do not have a universal patient identifier in common; exact matching of several linking variables applied all at once would have insufficient yield because of missing values (Table 1) and possible transcription errors. Thus, we applied a hierarchical deterministic method with different combinations of the linking variables to maximize linkage accuracy and yield while reducing the impact of missing values and errors (Table 2).

The underlying assumption for linking the GCASR and GDDS data is that no two subjects with similar demographic characteristics would be admitted to or discharged from the same facility on the same date with acute stroke (Table 3). Once the two data sets were linked, a 15 digit

alphanumeric code in the GDDS data, composed of letters from first and last name, birthdate and gender code, served as a quasi-unique identifier for each subject.

Testing Linkage Accuracy

We used records from the 2010 GCASR and GDDS data for assessing linkage accuracy. In 2010, 56 GCASR facilities had 11,043 acute stroke admissions. The highest number of admissions per facility per day was nine, and 47 hospitals had admitted two or more patients on the same day at least once. Among the 2010 discharges from non-federal and non-rehab facilities, 52,272 records of adults 18 years and older had an ICD 9 code of stroke (430-438) in one of the diagnosis fields and were used for linkage with the GCASR data.

The registry data is a subset of GDDS data and any subject from GDDS data with similar values in the six listed matching characteristics – facility, dates of admission and discharge, age, gender and race – would match with the registry data. It is, thus, appropriate and more informative to ask how many of the registry data failed to link and whether the linked GCASR records matched to the true hospital discharge record.

In 2010, about 70% of acute stroke patients in Georgia were treated at GCASR participating hospitals.¹ Assuming an 80% case ascertainment completion rate, the prevalence of GCASR reported acute stroke admission in Georgia would be greater than fifty percent. Hence, based on the method described by Buderer,² a sample of 277 subject would be enough to establish a sensitivity of 90% with 5% precision at 0.05 level of significance. Considering a two-third response rate, we increased the sample size to 430.

Hospitals around the Atlanta metro area account for about half (~ 52%) of the registry patients. Patient records were selected randomly from Atlanta area hospitals with 200 or more discharges of acute stroke in 2010. The first and last name, sex and birth date of sampled patients were recorded from the original hospital patient chart. The information was then used to construct the quasi-unique patient identifier (variable LONGID) that was subsequently compared with the same variable from the hospital discharge in the linked data file. The difference in the values of sex (between what was initially entered into the registry data and the one reported by hospitals for sampled patients) was calculated to quantify simple transcription error in data entry. The performance of the data linkage between the GCASR and hospital discharge data was assessed among the randomly selected patients' records using indices of sensitivity and positive predictive value. The proportions of registry records linked with GDDS data was analyzed in aggregate and separately for each hospital. The Fine-grained record integration and linkage tool (FRIL) software version 2.1.5 was used for data linkage.³

Results

GCASR had 11,043 records entered from 56 hospitals in 2010; 151 were transferred to another facility without admission. Among the 10,892 records, 10,536 had valid values of all the variables used for data linkage. Eighteen records had missing value for sex and 340 for race. Two hundred thirty-five patients were discharged within 24 hours. The matching algorithm resulted in linking 9,530 (88%) of the GCASR records with hospital discharges (Figure 1). Concordance in matching variables was greater than 96% between the two data sources (Table 4).

The proportion of linked records varied among hospitals participating in GCASR from 25% to 99%, the median being 91% with 76% and 94% first and third quartiles, respectively. Though not statistically significant, differences were observed among hospitals based on bed size and primary stroke center status (Table 5). Large hospitals and primary stroke centers had a relatively higher proportion of records matched with the GDDS data.

Information was gathered for 322 the randomly selected GCASR records. Sex and age were different from what was reported in the registry in 13 and 19 of the sampled records, respectively. Linkage resulted in 277 (99.6%) true matches and 1 (0.4%) mismatch; the remaining 44 were not linked to any record from the hospitalization data (Figure 1). The percentage of matched records varied among hospitals with a median of 92% (Q1=86%, Q3=96%).

Discussion

Results from the study showed that linkage between the registry and GDDS is highly specific. There was only one registry record mismatched with the hospital discharge. Examination of the record indicated a typographical error where an age 57 was entered instead of 75. The yield, on the other hand, is not comparable to the specificity. Nonetheless, given the percent of missing values (e.g. 3.3% race in the registry data) and data entry error (e.g. 5% age in registry data) observed in matching variables, the result can be considered satisfactorily high.

Given a 92% sensitivity in a previous study linking GDDS data with death data,⁴ the yield diminishes further when all the three data sources are linked together. We would expect to have about 80% (0.91×0.88) yield if we combine the registry data with GDDS and then with the death

records. If we are interested in estimating the occurrence of events such as death among patients admitted with stroke, we will underestimate the mortality rate. However, if a study aims to assess the impact of an intervention, for instance IV tPA treatment, and we compare those who received the treatment vis-à-vis those who didn't, then it is possible to compare mortality rates between the two groups, unless there is a reason to believe death in the two groups is captured differently by death record. Obviously, there will be a misclassification bias but it will be non-differential and will only diminish the effect measure towards the null value.

The small subset of randomly selected GCASR records showed that matching variables could have data entry errors. Depending on the number of variables used for matching, applying exact matching in each linking variable would diminish the yield significantly. Therefore, it is pragmatic to establish an iterative matching using a couple of blocking variables to maximize the return at the end of data linkage. The approach used in this study, the hierarchical deterministic linkage, becomes a necessity rather than a choice.

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Table 1 Percent of missing or implausible values in matching variables among the data sources

Variable	GDDS (2010)	GCASR Data	Variable	GDDS (2010)
Sex	0.0%	0.2%	LONGID	1.6%
Age	0.0%	0.0%	Birth date	0.0%
Race	0.0%	3.3%	Residence County	4.3%
Facility	0.0%	0%	Residence ZIP	4.3%
Discharge date	0.0%	0%		
Admission date	0.0%	1.4%		

GCASR: Georgia Coverdell Acute Stroke Registry; GDDS: Georgia Discharge Data System

Table 2 Key variables and their combination for matching the 2010 GCASR and GDDS data

Linkage Step	Linking variable	Distance metric (Approve/Disapprove level)	Acceptance level
Step I	Facility Admission date Age Sex	Equal fields Boolean distance Date Distance (+/- 0 day) Numeric distance (+/- 0) Equal fields Boolean distance	100%
Step II	Facility Admission date Age Race	Equal fields Boolean distance Date Distance (+/- 0 day) Numeric distance (+/- 0) Equal fields Boolean distance	100%
Step III	Facility Discharge date Age Sex	Equal fields Boolean distance Date Distance (+/- 0 day) Numeric distance (+/- 0) Equal fields Boolean distance	100%
Step IV	Facility Discharge date Age Race	Equal fields Boolean distance Date Distance (+/- 0 day) Numeric distance (+/-0) Equal fields Boolean distance	100%
Step V	Facility Admission date Discharge date Race Sex	Equal fields Boolean distance Date Distance (+/- 0 day) Date Distance (+/- 0 day) Equal fields Boolean distance Equal fields Boolean distance	100%

N.B.:-

- Facility is the blocking variable
- GCASR: Georgia Coverdell Acute Stroke Registry; GDDS: Georgia Discharge Data System
- Exclude those with
 - Missing admission date
 - Age differences > 1yr
 - Admission date difference > 1 day

Table 3 Specificity of combinations of facility, demographic and event related information

Combination	Total	Unique	Non-specific
GCASR data (N = 11,043)			
Facility, Admission date, Age	10,881	10,723	158
Facility, Admission date, Age, Race	10,943	10,844	99
Facility, Admission date, Age, Sex	10,962	10,884	78
Facility, Admission date, Age, Race, Sex	10,991	10,940	51
Facility, Admission date, Age, Race, Sex, Discharge date	11,023	11,003	20
GDDS data (N = 52,272)			
Facility, Admission date, Age	50,855	49,482	1,373
Facility, Admission date, Age, Race	51,405	50,549	856
Facility, Admission date, Age, Sex	51,531	50,804	727
Facility, Admission date, Age, Race, Sex	51,838	51,407	431
Facility, Admission date, Age, Race, Sex, Discharge date	52,218	52,164	54

GCASR: Georgia Coverdell Acute Stroke Registry; GDDS: Georgia Discharge Data System

Table 4 Agreement in matching variables

Matching Variable	2010 GCASR Vs. GDDS
NAME*	98.4%
Birth Date	98.4%
Age	98.4%
Sex	99.3%
Race	96.7%
Facility	100.0%
Admission date	96.2%
Event/Discharge date	97.1%

GCASR: Georgia Coverdell Acute Stroke Registry; GDDS: Georgia Discharge Data System

*: refers to a 6-digit code derived from names

Table 5 Average percentages of GCASR records matched with hospital discharges by hospital characteristics

Categories	Median	1 st . Quartile	3 rd . Quartile
Bed size			
<= 100 beds	79.6%	65.6%	91.9%
101-250 beds	87.0%	70.6%	94.9%
251 - 400 beds	92.4%	90.9%	95.0%
> 400 beds	91.1%	87.9%	93.9%
Primary Stroke Center Status			
PSC	92.0%	87.0%	94.8%
Non-PSC	82.9%	66.9%	93.4%

GCASR: Georgia Coverdell Acute Stroke Registry; PSC: Primary Stroke Center

What is missing is

Change the reference numbers in the text

Change the expression for composite measure in the second manuscript

Finalize the list of tables and figures

Figure 1. Georgia Coverdell Acute Stroke Registry Records linked with Hospital Discharge data, 2010

