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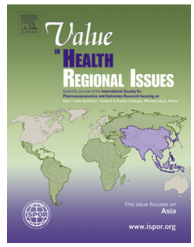

Treatment Costs of Stroke Related to Nonvalvular Atrial Fibrillation Patients in India—A Multicenter Observational Study

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ABSTRACT

Objective: The objective of this study was to quantify the direct medical and nonmedical costs of stroke among patients with nonvalvular atrial fibrillation in India. **Methods:** An observational, multicenter cost-of-illness study was conducted within large tertiary care hospitals across three metropolitan cities in India. Medical chart records of eligible patients who were hospitalized during the study period were reviewed. A standardized data collection form was designed and used to capture resources expended in the treatment and management of stroke during the inpatient stay. In addition, direct medical and nonmedical outpatient care resources and informal care burden were captured using a detailed questionnaire, following the patients' discharge. Factors associated with acute care costs were investigated using multivariate linear regression analysis. **Results:** Data were collected on a total of 400 patients with incident strokes. Their mean age was 61.4 ± 9.4 years. About 84% of the patients were diagnosed with ischemic stroke. On average, patients spent 16 ± 10 days in the hospital. Total mean direct health care costs per patient amounted to `504,973 (US $8,020) during the first year, with about 47% (mean `235,471; US $3,750) of the total costs due to the index hospitalization. The modified Rankin scale score was strongly associated with costs, whereby severely disabled patients had 32% higher costs ($P = 0.001$) compared with moderately disabled patients during the first 3 months postdischarge. **Conclusions:** Overall, the financial burden associated with medical care for patients with stroke with atrial fibrillation along with rehabilitation and long-term care costs places a significant demand on health services in India.

Keywords: cost, cost of illness, India, nonvalvular atrial fibrillation, stroke.

Introduction

Stroke occurs when interruption of blood supply or leakage of blood from a blood vessel causes damage to the brain [1]. Every year, 20 million people worldwide experience a stroke, making it one of the fastest growing causes of morbidity and mortality [1–5]. Stroke is a predisposing factor for epilepsy, falls, and depression [3] and is a leading cause of functional impairments, with 20% of the survivors requiring institutional care after 3 months and about 15% to 30% permanently disabled [6]. Stroke is no longer considered a condition that affects the developed world. Globally, 12.6 million people suffer moderate to severe disability after stroke and of this, 8.9 million people are from low- and middle-income countries [3]. Low- and middle-income countries in the Asia-Pacific region account for 85.5% of total stroke deaths worldwide, and the number of disability-adjusted life-years in these countries is reported to be seven times that observed in high-income countries [7]. It is estimated that in India alone about 6.36 million disability-adjusted life-years are lost because of stroke [8].

China and India have the largest populations in the Asia-Pacific region and account for the highest numbers of deaths from stroke (18,16,000 and 7,27,900, respectively) [9,10]. The prevalence of stroke in India is reported to be 99 to 222 per 100,000 [10], with about 1.44 to 1.64 million cases of new stroke diagnosed every year [3,11]. Furthermore, studies have reported that the average age of patients with stroke in developing countries is 15 years less than that in developed countries [12]. Results from studies conducted in India have shown that about 10% to 15% of strokes occur in people younger than 40 years, with about 21% to 48% of strokes being caused by atherosclerotic large artery occlusive diseases [11,13]. Although stroke mortality rates are declining or stabilizing in developed countries, experts are concerned about the emerging epidemic of stroke in India [14]. As life expectancy is projected to increase, India will likely face a significant socioeconomic burden to meet the cost of managing stroke [15]. A recent study identified that 7% of medical and 45% of neurological admissions were due to stroke, with a fatality rate of 9% at hospital discharge [16].

Conflict of interest: The authors have indicated that they have no conflicts of interest with regard to the content of this article.

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Atrial fibrillation (AF) is an important risk factor for stroke [17–20]. Compared with the general population, people with AF have a fivefold increased risk of stroke [17,18]. AF is responsible for about 20% of ischemic strokes [17–20]. The risk of stroke in patients with AF increases with age and with the addition of other risk factors (e.g., high blood pressure, age > 75 years, congestive heart failure, previous stroke or transient ischemic attack or thromboembolism, and diabetes) [21–23]. AF-related strokes are predominantly cardioembolic, more severe, and cause greater disability and have worse outcomes (20% likelihood of death and 60% disability) than does stroke in people without AF [17–20,24,25]. Given that AF-related strokes tend to be more severe, they result in higher direct medical patient cost annually compared with non-AF–related stroke. The total societal burden of AF-related stroke reaches €13.5 billion per year in the European Union alone [26,27]. Furthermore, this financial burden is higher for patients and their families in countries such as India where there is a greater level of out-of-pocket expenditure on health care.

Cost-of-illness studies highlight the economic magnitude of an illness/condition on society or a part of society. These studies have been frequently used by policymakers such as the National Institutes of Health and the Centers for Disease Control and Prevention in the United States and have been used in part to describe resource allocations for various diseases [28]. Because limited data are available regarding resource utilization and costs associated with the management of stroke in India, the objective of the current study was to estimate the average direct medical and nonmedical costs of stroke among patients with nonvalvular AF.

Methods

Study Overview

An observational, multicenter cost-of-illness study was conducted at hospitals offering specialty services in neurology across three metropolitan cities, namely, Gurgaon, Mumbai, and Bangalore in India. Based on the Sancd report (2008), these cities had reported a high prevalence of stroke cases. A site feasibility analysis was conducted in each city, and chief medical officers from hospitals that met the study criteria were contacted to understand their interest in participating in the study. Hospitals were selected on the basis of factors such as bed size, presence of neurology/stroke unit ward, availability and access to patient medical charts and discharge records, ethics committee approval process, and willingness of the key opinion leader and hospital to participate in the study. Hospitals that consented to participate in the study were the Holy Family, Saifee, and Lilavati hospitals in Mumbai; St. John's Medical College in Bangalore; and the Medanta Institute of Neurosciences in Gurgaon. The study was conducted from a societal perspective and was approved by the hospital ethics committee board at each participating center. All participating patients completed an informed consent form at the start of the study.

Patient inclusion criteria for the study were as follows: diagnosis of ischemic or hemorrhagic stroke (primary and recurrent) for patients older than 18 years, a prior diagnosis of AF, AF with at least one additional risk factor (i.e., previous ischemic stroke, transient ischemic attack, or systemic embolism, left ventricular dysfunction, age ≥65 years, with either diabetes mellitus, history of coronary artery disease, or hypertension). Patients were excluded from the study on the basis of evidence of any of the following conditions: 1) cancers, fatal renal, hepatic, or respiratory insufficiency; 2) disabling and progressive neurological diseases (multiple sclerosis, Parkinson's disease); 3) dementia; and 4) refusal or withdrawal of patient informed consent to participate in the study.

Medical chart records of patients who met the above inclusion criteria and were hospitalized from January 1, 2010, through December 31, 2011, were reviewed. A standardized data collection form was designed to capture demographic and clinical characteristics of patients and resources expended for the treatment and management of stroke during their inpatient stay from patient medical charts. The data collection form captured information on the following parameters: patient demographic characteristics, medical history/comorbid conditions, pharmacological management, surgery, diagnostic/laboratory tests, and hospital length of stay (LOS). Because India is predominantly an out-of-pocket payer market, there are limited data, if any, available on hospital charges; therefore, hospital costs were derived from per patient billing records at each site. All prices are 2012 values. A trained on-site reviewer performed data collection at each participating center. All case report forms were verified for completeness and accuracy of data. Data collected for the study were de-identified and kept confidential at an onsite password-protected secure server.

Structured interviews using the modified Rankin Scale (mRS) [29] were conducted to assess the functional disability due to stroke among all participating patients within 1 week of hospital discharge. The mRS is a global disability scale used to measure the degree of disability or dependence in daily activities of people who have suffered a stroke or have other neurological disabilities. It is a commonly used clinical outcome measure for stroke in clinical trials with a scale from 0 to 6, where 0 indicates "no symptoms" (perfect health) and 6 indicates "death."

Because no data were available regarding outpatient resource use and cost associated with stroke postdischarge, two questionnaires—one to be completed by participating patients and the other to be completed by physicians—were developed. Patients who met the inclusion criteria and agreed to participate in the study completed the questionnaire at 3 months postdischarge via telephonic or face-to-face interviews. The questionnaire captured information regarding the frequency of clinic visits with neurologists, cardiologists, or general practitioners, laboratory and imaging tests, rehabilitation services (physiotherapy, speech therapy, etc.), specialized nurse services, additional stroke-related hospitalizations, and stroke-related medications (name, dose, and frequency were obtained by asking the patients to refer to their prescription records). Patients were also requested to provide estimates for travel costs incurred to obtain medical services and modifications made to their home poststroke during this period. Patients receiving informal care from caregivers were requested to estimate the cost of informal care on the basis of the number of days of lost productivity (unpaid leave) by the caregiver. Outpatient cost for each patient was estimated by multiplying the average cost for each resource unit by its frequency for the acute 3-month period postdischarge.

The physician questionnaire captured data for outpatient services such as the frequency of outpatient clinic visits, laboratory and imaging tests, and stroke-related medications over the remaining 9 months after the "acute phase." This questionnaire was completed by five neurologists from the three cities where the study was conducted. Outpatient costs for this period were calculated by multiplying the average per visit/service costs by the total number of visits/services used over the 9-month period. While estimating the annual costs in the study we assumed that no patient had a recurrent stroke event during the study period. Table 1 shows a list of health resource items investigated and outlines the resources that were estimated in the study.

Statistical Analyses

Statistical analyses were conducted with SPSS version 19.0. Descriptive analyses were used to describe the continuous and