Evaluating the Outcomes of Stroke

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Stroke places a major burden on society in terms of mortality, morbidity and economic costs. More than 700,000 Americans suffer a stroke each year and over 400,000 survive with varying degrees of disability. Stroke is the most common cause of adult disability and the third leading cause of death. The direct costs of treating individuals with stroke have a major impact on health care. In 1993, the total cost of stroke in the United States was over $30 billion dollars and the estimated annual cost for rehabilitation services was over $7 billion. Forty-four percent of all Medicare inpatient rehabilitation expenditures are attributable to stroke.

Despite a decline in stroke mortality, the incidence of stroke is not declining. A recent study indicated that initial stroke severity in a population of stroke patients was very severe in 19%, severe in 14%, moderate in 26% and mild in 26%. More individuals are surviving with mild and moderate deficits. Even individuals with mild and moderate stroke are left with significant disabilities and lower quality of life. An assessment of the health status of individuals with mild stroke who were community-dwelling and independent in activities of daily living compared to a group of individuals who had not experienced a stroke but had stroke risk factors, revealed that the stroke group was more impaired in every dimension of health status except pain.

Selecting outcome measures for stroke is extremely complex. Clinical and health-related quality of life outcomes of stroke can be classified into impairments, disabilities and handicaps. Impairments are the signs and symptoms of the underlying pathology, disabilities include limitations in functional activities and handicaps refer to limitations in role functions. Common stroke-related impairments include motor deficits, abnormal sensation, aphasia, visual-spatial neglect, cognitive deficits, depression and affective changes. Disabilities can occur in mobility, self-care or the ability to manage higher levels of activities such as managing finances or medications, shopping or driving. Handicap, at the societal level, is defined as a disadvantage for a given individual that limits or prevents him or her from fulfilling a role that is normal (depending upon age, sex, social or cultural factors) for that individual. Ideally, recovery from stroke-related impairments leads to recovery from stroke disabilities, reduction of stroke handicaps and ultimately, to premorbid levels of quality of life but this is not always the case.

Stroke is a difficult disease to study because of its differing etiologies, the heterogeneity of symptoms, variability in severity and in spontaneous recovery. Additionally, it is difficult to ascribe the reasons underlying recovery from stroke because they may be neurological, adaptive or a combination of both.

Stroke recovery reflects three simultaneous and interrelated processes: 1) resolution of acute pathological sequella of stroke, 2) resolution of intrinsic neuroplasticity and 3) behavioral compensation. These three processes often produce recovery patterns in which neurological and functional recovery do not necessarily correlate with one another, i.e., there may be functional recovery without much neurological improvement or vice versa. The time course of neurological recovery tends to follow a pattern similar to functional recovery. However, many patients may experience substantial functional recovery in the presence of major neurological deficits.

The initial severity of stroke is highly predictive of eventual outcomes and the time course of recovery. Patients with the most severe stroke will experience the least amount of recovery, individuals with moderate stroke will have the most variability in their recovery and patients with mild deficits have the most recovery. Because of the variability among the subgroups of stroke...
patients, outcomes studies should stratify patients into different categories based on the degree of the initial severity of their stroke. In addition, in some cases it may be preferable to select outcome measures on the basis of the patient’s severity of stroke. For example, if most people with mild strokes achieve independence in activities of daily living (ADL), measures that focus exclusively on ADL and not higher level activities may not discriminate between the differences in outcomes across groups of patients with mild deficits.

Patients with mild strokes who achieve independence in ADL may, however, have residual deficits in higher levels of physical functioning, e.g., instrumental activities of daily living and role functioning. The most commonly used outcome measure in stroke, the Barthel Index, is a measure of ADL. Preliminary results from the Kansas City Stroke Study reveal that the Barthel Index has a ceiling effect in stroke patients with milder impairments. In such cases, other measures like the MOS SF-36 may be more appropriate in an outcomes measurement strategy. In contrast, the physical function domain of the SF-36 has a significant floor effect for patients with severe strokes, i.e., a large proportion of patients with a severe stroke will be grouped at the lowest SF-36 scores.

To date, there is no consensus about what are the “best” health status and outcomes measures to use to reflect the effects of stroke. A recent review of 174 acute stroke trials revealed that most trials (72%) measured stroke-related impairments, 42% measured disability impairments and only 2% measured handicap or health-related quality of life. Many of the trials used measures that did not have proven reliability and validity. Additionally, when disability was measured as a dichotomous variable, there was no standardization among the definitions that were used to indicate a ‘good versus a bad’ outcome. Thus, much work needs to be done in stroke assessment to advance the underlying science, selection and use of stroke outcome measures. Two important initiatives are currently underway that aim to improve our ability to assess patient outcomes of stroke.

Stroke Outcome Scale: The American Heart Association (AHA) Stroke Outcome Classification Task Force developed a global classification system to summarize the neurological impairments and disabilities associated with stroke. The first area of assessment is about the number and severity of impairments in a range of neurological domains including motor, sensory, vision, language, cognition and affect.

The second component of the AHA classification system is about disability and function. It includes five levels and assesses basic self-care, mobility, more complex instrumental activities of daily living, as well as an individual’s ability to live alone and other indicators of role functioning, e.g., the ability to access the community for leisure and engage in productive activities such as volunteer work.

Stroke Impact Scale: Due to the limitations in currently available measures of stroke outcomes, investigators at the University of Kansas Medical Center’s Center on Aging, with a partial funding by GlaxoWellcome Pharmaceuticals, have developed a stroke-specific outcome measure, The Stroke Impact Scale (SIS). The SIS was developed to respond to changes in patient status over time in clinical trials, e.g., with rehabilitation and pharmacological interventions, used to treat stroke. The instrument was developed with two major goals in mind: 1) to have strong clinical relevance for patients and clinicians and 2) to focus on stroke-related impairments, disabilities and handicaps. The items in the survey were generated to represent patients’ and caregivers’ perspectives and to be responsive to change in individuals who sustain mild and moderate strokes. To date, the instrument development process has included ten phases including interviews and the conduct of focus groups with patients and experts in stroke, work by two consensus panels and pilot testing.

The current phase of the project involves the prospective administration of the SIS at one, three and six months post stroke with a sample of 100 subjects enrolled in the Kansas City Stroke Study. The goal of this work is to reduce the number of items in the instrument and to evaluate its concurrent validity, test-retest reliability and sensitivity to change by December 1, 1998. The SIS will be compared to existing measures of stroke outcomes including the National Institute of
Health Stroke Scale, the Fugl-Meyer Assessment of Motor Function, the Barthel Activities of Daily Living, the Functional Impairment Measure and the Lawton Instrumental Activities of Daily Living Scale.

Conclusion: To date, there is no consensus about the best measure of stroke outcomes. Any stroke outcome measure that is selected should have relevance for clinicians and patients, strong psychometric properties and be responsive to change. Since there is no simple relationship between impairment, disability and handicap, it is important to use outcome measures that represent all three of these constructs if we are going to fully understand the impact of stroke. Outcome measures should include items relating to a single level of severity of stroke to avoid the confounding of information.