Health Policy and Outcome Research in Stroke

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Health policy research seeks to inform clinical and public policy related to stroke prevention, treatment, rehabilitation, and long-term care. This review is not intended to be comprehensive but to highlight some of the recent studies that address important areas of stroke service provision.

Organized Stroke Care

We have just passed the 10th anniversary of the publication of the meta-analysis by Langhorne et al showing that stroke units save lives. Since then further trials have reinforced this message showing that the benefits of organized stroke care are evident regardless of the type or severity of the stroke or the age of the patient. Of particular importance is the demonstration that the benefits are very long lasting. Reducing the odds of death by nearly 20% and death and dependency by nearly 30% stroke unit care is one of the most powerful interventions we currently have available and one that can be implemented without imposing a major financial burden on health care providers. Despite this, the evidence from Europe suggests that few countries have succeeded in providing the majority of stroke patients with specialist care. In the United Kingdom only 36% of patients are managed at any time during their hospital stay on a stroke unit, in France 4%, Germany 30% and Italy 9%. Only in some of Scandinavian countries do figures approach acceptable levels with 60% in Norway and 70% in Sweden.

In England political pressure is being used to influence change within the health service. By April 2004 the Department of Health has stated that all hospitals should have a stroke unit, although it has stopped short of demanding that the units should be large enough to accommodate all patients. National audit has proved a powerful tool for driving change, but it remains a slow process. The European Union Stroke Initiative (EUSI) has published updated guidelines for care which reinforce the need for patients to be managed by specialists. Adherence to guidelines for the use of thrombolysis is a clear example of how inadequate care can directly lead to increased mortality and morbidity. The Cleveland experience, where initial introduction of thrombolysis into general hospitals, with frequent protocol violations led to very high rates of intracerebral hemorrhage, provides clear lessons. This year they report the effect of a quality improvement program showing a reduction of protocol violations from 50% in 1997 to 1998 to 19.1% in 1999 to 2000, leading to hemorrhage rates falling to levels consistent with those seen in the NINDS trial of 6.4%. Applying the strategies demonstrated to be effective in the NINDS trial has also been demonstrated to be cost and clinically effective. Developing and implementing guidelines for nutritional support after stroke has also been shown to be effective, particularly in reducing infective episodes. A Cochrane review of in-hospital care pathways for stroke, however, shows that there is no evidence that implementing a pathway improves outcomes in terms of death, dependency, discharge destination, or length of stay. The process of care was improved with higher rates of brain and carotid imaging and hospital readmission rates reduced. The data on which the review is based are limited. There have been only 3 randomized trials totalling 340 patients and 7 nonrandomized trials. It seems likely that the largely negative results reflect underpowered, flawed studies. It is debatable whether there is value in subjecting an intervention that is intuitively correct and unlikely to be associated with harmful effects to further randomized trials. The time has come where it is accepted that well-organized, professionally delivered care is better than inadequate disorganized care.

Attempts to compare the quality of care between clinical centers are becoming more widespread. For stroke it is not as straightforward as for simpler interventions such as surgery. Stroke is a complex disease, often occurring in people with multiple comorbidities and with interventions required that have not been tested in randomized controlled trials. For simple outcomes such as death or disability, statistically significant differences due to variation in treatment interventions would often require large numbers of patients needing long periods of time to collect. Clinicians if not politicians therefore prefer collecting data on process of care, where such processes have been shown to affect outcome in randomized trials. Unfortunately McNaughton et al, conducting a prospective study in New Zealand looking at the relationship between process and outcome in stroke, found little evidence of a link; in fact, the hospitals with the best process scores had the worst case mix-adjusted outcomes. Defining how best to measure the quality of care needs further research.

Organization of Care After Transient Ischemic Attacks

There have been few community based registers of patients with transient ischemic attacks (TIA). The Oxford Community Stroke Project is one of these and reported in the mid-1980s a risk of 1% to 2% of stroke at 7 days and 2% to...
4% at 1 month. This estimate, however, was based on a pragmatic analysis of risk after presentation to medical attention and referral to hospital, often days or weeks after the TIA. This approach to case finding ran the risk of missing patients who had stroke very early after TIA. The data has now been reanalyzed\(^\text{15}\) to estimate the very early stroke risk and investigate the potential effects of delays before specialist assessment. The results make disturbing reading for those running services for patients with TIA. The risk of stroke from first ever TIA were 8.6% at 7 days (95% CI 4.8 to 12.4) and 12% (95% CI 7.6 to 16.4) by 30 days. TIA should therefore be managed as a medical emergency, equivalent to the way in which acute coronary syndrome is dealt with by cardiologists. These data suggest that patients should be seen investigated and given appropriate treatment, including, if necessary carotid endarterectomy, within a maximum of 7 days after the first symptom. This will require services to be reconfigured in many countries. In the United Kingdom, patients are rarely admitted to hospital after TIA and waiting lists for specialist clinics may be several weeks. If patients are not to be admitted to hospital urgently, then one stop clinics running several times a week with no waiting lists will need to be provided. There will also need to be a program to educate the public as to the correct response to sudden onset of focal neurological symptoms.

It is widely believed that vertebrobasilar (VB) TIs are less likely to lead to completed stroke than carotid territory events. A meta-analysis shows this to be myth.\(^\text{16}\) Population based studies show that VB events actually have a higher risk of stroke (OR 1.48, 95% CI 1.1 to 2.0, \(P=0.025\)). These patients should therefore also be managed as medical emergencies.

### Improving the Treatment of Carotid Disease

Carotid endarterectomy has been established as both effective and cost-effective in symptomatic patients with high-grade carotid stenosis; the net value and cost impact are less evident for asymptomatic patients.\(^\text{17}\) Recent work has sought to improve this situation by reducing the risk of the procedure, or by introducing an alternative such as carotid artery stenting. Recognizing that the health and economic impact of carotid surgery hinges on the safety of the procedure, investigators have examined the relationship between procedure volume and the complication rates following surgery. In one study based on the National Inpatient Sample,\(^\text{18}\) previous findings of a volume-outcome relationship were supported (OR 1.9, CI 1.4 to 2.5). This would support a policy of directing patients to surgeons and institutions based on volume. However, this is not supported by data from the Department of Veterans Affairs National Surgical Quality Improvement Project. An analysis of this prospective cohort of surgical patients, rates of 30-day complications in one 2-year period were weakly correlated with rates in the subsequent 2-year period.\(^\text{19}\) This should raise concern that a broad policy of limiting where surgery can be performed and by whom—purely based on volume—does is not justified, and could have untoward effects, such as reduced access to care.

One strategy for improving the cost-effectiveness of the treatment of carotid disease is to directly reduce cost of surgery without affecting the benefits. In a retrospective study, Gurur et al report that use of local rather than general anesthesia was associated with a nearly 50% reduction in length of hospital stay and a reduction in cost of approximately 10%.\(^\text{20}\) Another strategy for improving the cost-effectiveness of the treatment of carotid surgery is to use carotid stenting as an alternative. Based on preliminary data on stenting, Kilaru et al\(^\text{21}\) estimate the cost implications of carotid stenting compared with carotid endarterectomy. Due primarily to the cost of complications, stenting was dominated; compared with carotid endarterectomy, stenting cost $7027 more and reduced the benefit to the patient by 0.16 quality-adjusted life years. Stenting would only be cost effective if the complication rate with stents could be dropped significantly. Clearly, the policy impact of this new technology is still to be determined.

### Predicting Stroke Outcome

Statistical models to predict the outcome after stroke are of little value in the management of individual patients and can be harmful if they are used to determine access to treatment. They do, however, have a role in predicting outcome for groups of patients, for example in adjusting for differences in baseline characteristics in multicenter trials or in stratifying patients at baseline to increase the likelihood of balance between different treatment groups. The FOOD Trial collaboration\(^\text{22}\) report the validity of a predictive model in a large randomized trial evaluating feeding policies in patients with stroke. The model using 6 easily collected variables (age, prestroke independence, living circumstances, and 3 factors reflecting stroke severity), performed well, especially when the data were collected within the first day of stroke. This model is more straightforward, has greater validity and has been more widely tested than many previously reported. Stroke research would be well served by the widespread introduction of a uniform system for defining case mix to help in the comparison of results between trials. This model provides such an opportunity.

### Inequalities in Stroke

Socioeconomic factors are well recognized as influencing the incidence and outcome of stroke. Horner et al\(^\text{23}\) from the United States found no differences in access to inpatient rehabilitation services between black and white patients and van den Bos in the Netherlands no differences in access for patients from different social classes.\(^\text{24}\) Patients with lower socioeconomic status were however more likely to be admitted to institutional care. Aslanyan et al\(^\text{25}\) found little evidence in Scotland that social deprivation affected case fatality, although high deprivation scores were associated with more severe stroke and hospital readmission. There is an association between socioeconomic status and atherosclerosis, including carotid disease. This has been confirmed in a Scottish study, which has also shown that the increased incidence of potentially surgically treatable disease in poorer areas is not matched by an increase in the rate of carotid endarterectomy.\(^\text{26}\) Two studies have reported that female sex is associated
with reduced access to appropriate management. Di Carlo et al., analyzing data from a multicenter study from 7 countries in Europe, show that brain and carotid imaging, echocardiography, angiography, and carotid endarterectomy were significantly less likely to be performed in women. At 3 months, women were more disabled and more severely handicapped than men. These differences persisted after adjustment for age. A Swedish study, analyzing data from their national register in which all hospitals participate, shows that after adjustment for age, females were more often disabled before the stroke and were also more severely affected at 3 months after the stroke. As a marker of the quality of care, female patients with atrial fibrillation were less likely to be anticoagulated than men.

The qualitative literature on inequalities in stroke care has recently been reviewed by Mold et al., suggesting a number of areas where further research is required. It is clearly unacceptable for access of care to be rationed according to age, sex, race, or income and one of the key roles of audit should be to continue to monitor equality of access to treatment.

**Early Supported Discharge**

The feasibility of discharging patients after stroke early, substituting care on an inpatient stroke unit with specialist treatment at home has been demonstrated in a number of studies over the past few years. Clinical outcomes are equivalent, with possibly some cost savings. Fjaer Toft et al. report the 1-year follow-up data from a randomized controlled trial of 320 patients that demonstrates the early discharge group had greater levels of independence than those managed in hospital. Patients with moderate to severe stroke benefited from early discharge most. Further advantages to early supported discharge have been identified by Teng et al., who show that their scheme in Canada reduces the burden of care even for patients with major functional limitations and is significantly cheaper than usual care. The evidence base for early supported discharge is now sufficiently strong to justify it becoming a mainstream part of every stroke service.

**Costs of Stroke and the Value of Prevention**

Recent studies have reinforced the fact that stroke is expensive, expenditures are quite variable from country to country, and stroke prevention is a good use of health care resources.

Aggregating from multiple data sources, the American Heart Association has released US estimates of stroke cost for 2003. Direct costs, including hospital, nursing home, physician, drug, and home health costs total $31 billion; with the addition of productivity losses, the estimated total cost of stroke exceeds $51 billion. Levy et al. compared stroke care costs in European countries. While noting differences in the costs for acute care among the countries were small, variations in rehabilitation costs resulted in a 10-fold variation in cost of follow-up care. A recently published study from the Netherlands describes an issue that has not been well documented—the impact of stroke on use of mental health resources. Indeed, stroke appears to contribute measurably to national mental health facility costs. It will be important to further investigate this phenomenon, as some aspects of stroke—especially post-stroke depression—are common and potentially treatable.

Concerning the economic impact of prevention, 3 cost studies from different country perspectives have been published from results of the Heart Outcomes Prevention Evaluation (HOPE) study, an evaluation of the angiotensin-converting enzyme inhibitor (ACEI) ramipril, in high-risk cardiovascular patients. In an analysis from the US and Canadian perspectives, Lamy et al. noted that ramipril is highly likely to be cost effective (in a bootstrap analysis they estimate a 90% likelihood that treatment would be either cost saving or have an incremental cost-effectiveness ratio below $10,000). In a separate analysis, Carroll et al. report that from the US perspective, the stroke reduction effect indicated by the primary HOPE results translates into a 2-year cost saving of $52,861 for 21 strokes prevented. A model-based analysis from the Spanish context suggested that the use of this ACEI would not be cost saving but would be cost-effective (10,329 euros per life year gained).

**Use of Modeling in Evaluation of Stroke Policy Strategies**

Cited elsewhere, the study by Stahl et al. is notable for its use of a promising method that has only been used to a limited extent in medicine—discrete event simulation. This approach allows one to analyze the potential impact of changes in waiting times related to process modifications. In this case, maintaining waiting times from door to treatment to within NINDS recommendations were projected to improve the proportion of treatable patients from 1.4% to 3.7%. Notably, this simulation suggested that an even more profound impact could be achieved by reducing time from stroke onset to arrival in the emergency department (reduction to 30 minutes could increase the proportion of treatable patients to 7.7%). This should not cause us to discount efforts to improve in-hospital performance, but should encourage greater attention to delays in getting patients to hospital.

In a notable report, Sundberg and colleagues extend previously described efforts to construct stroke simulation models, applying such models to decision making by health planners and policy makers in Sweden. Successful application of the Swedish model should encourage analysts and policy makers in less analytically inclined countries to collaborate on integrating well-constructed and validated models into stroke policy making.

**References**


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