Round Table: Cardiovascular Health

Designing a population based study of stroke: challenges and solutions

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Summary

A population based stroke study of urban and rural areas ('Stroke Epidemiology in A Rural CoHort – SEARCH') is being mounted in South Australia. The study aims to identify and compare the incidence, investigations, management and outcome of stroke between city and country groups. Criteria are well established for the design of population-based studies of stroke. This paper discusses how we are attempting to overcome the obstacles faced when applying these principles in metropolitan and rural Australia.

Introduction

Stroke is the third largest cause of death and a major cause of disability in developed countries.[1] The risk of stroke dramatically increases with age, having alarming implications for populations that are ageing rapidly. By the year 2020 stroke and heart disease combined will account for the greatest loss of healthy life-years.[2] There is a continuing need for reliable population-based epidemiological data on stroke to guide the provision of services to the community.

Sudlow and Warlow have identified criteria for 'ideal' epidemiological studies of stroke.[3] There have been two landmark Australian studies meeting these criteria in the last 20 years – the Perth Community Stroke Study (PCSS) running from 1989 and the North East Melbourne Stroke Incidence Study (NEMESIS) in the 1990s.[4, 5] There are no epidemiological studies of stroke meeting the 'ideal' criteria in rural populations of Australia and no urban studies in the last decade.

We are part of a collaborative group established to undertake an 'ideal' study of stroke simultaneously in rural and metropolitan South Australia. The project stands to provide valuable, up-to-date data on the incidence, investigation, treatment and outcome of stroke in both settings.

To meet established criteria an epidemiology study of stroke must occur in a large, stable, defined population, be performed prospectively and incorporate active community surveillance.[3] Identifying strokes that occur in a defined population requires detailed monitoring of many health care providers. Applying these criteria in a rural study is a significant challenge.

Defining the population

A large, stable, well defined population must be established where research is practical. Exploiting the clinical and academic ties with a stroke unit, our urban study population of 150,000 is defined by postcodes surrounding a major hospital. Both the PCSS and NEMESIS used such an approach. The rural arm of the project was defined around the participating workforce through links with rural medical schools. Comprised of scattered rural centres around the state, the size of the rural group is an equivalent though slightly younger 150,000 people. Studies of the incidence of stroke should run for at least one year to account for seasonal variation but, to boost power, SEARCH will cover two years.

Challenges of surveillance

Since some stroke victims never attend hospital, surveillance must occur in the community. There are many reasons why patients with stroke may not present to hospital. Whilst self report mechanisms can be arranged, it is known that active community surveillance must take place to capture stroke events reliably.[3]

Furthermore, although there may be a 'main' public hospital for a given area, patients may attend other public or private hospitals in the region. Even within hospitals there are challenges of surveillance. Not all strokes are referred to stroke services, some are palliated, other stroke events might be ignored in the context of other illness and some may be managed by general physicians.

In order for SEARCH to succeed, we must implement a comprehensive surveillance strategy in each region of the study area. This will involve surveying hospital admissions, emergency departments, ambulance calls, radiology, nursing homes and general practitioner visits. In addition, we will scan the death register regularly. Multiple avenues of ascertainment necessitate multiple ethics approvals. Contact networks have to be established to obtain information through different institutions and departments.

A new set of challenges occur when this process is to be undertaken in rural Australia. Massive distances require that investigators reside in areas of low population density. To solve this problem the SEARCH study will take advantage of the rural arms of the medical schools in South Australia by employing, on a paid voluntary basis, senior students rostered on rural placements throughout the year. This will provide a motivated workforce in remote regions, but creates further challenges in

training and supervision. In smaller communities, where privacy is difficult to achieve, surveillance strategies have to be sensitive. Losing community goodwill would make research impossible.

Diagnostic problems

Diagnosing stroke can be difficult. Strokes can be dismissed as a transient ischaemic attack (TIA) where more detailed examination would reveal persisting deficit. Conditions mimicking stroke, such as migraine, also confound diagnosis. It is established that all cases of TIA occurring in the study population should be seen by the research team for a reliable population-based study of stroke.[3] Different patients will have different investigations leading to more or less support for any given diagnosis. Each case entered into SEARCH will be reviewed with a neurologist through a video conference to ensure optimal accuracy.

Estimating work load

To distribute resources and estimate statistical power, an attempt must be made to anticipate the numbers of strokes expected. An overview of population-based registers of stroke found 15 studies, including the PCSS and NEMESIS, meeting the 'ideal' criteria.[6] The two Australian studies had relatively similar age-specific incidence rates. Applying data from PCSS and the NEMESIS to the demographic profile of our urban zone, we expect to register up to 800 strokes from Adelaide over two years.[4, 5]

In a prospective audit of presentations to the main public hospital within the urban zone, we identified 87 strokes in the study population in a 4-month period during summer. Ignoring seasonal variation, if the overall incidence of stroke is similar to NEMESIS and the PCSS, we can expect around two thirds of relevant events to present to the main catchment hospital. In the PCSS up to 40% of the more elderly patients did not attend hospital with their stroke.[7] Similar estimates can be calculated for the rural arm of the project. If the age-specific rates are similar to PCSS and NEMESIS, 550 to 600 strokes would be expected in the rural arm during the 2 year study period.[4, 5]

Defining the optimum data-set

Designing the data-set requires a balance of competing interests. First, by using many investigators across large distances, the variables must be both clear and standardised. Second, the information obtained should be comparable to previous population studies of the incidence, investigation, treatment and outcome of stroke. Third, the study should incorporate topical secondary objectives exploiting the urban and rural comparison. Finally, the survey must not take too long for the many part-time investigators at remote sites. If the burden is too great, the project is likely to fail. A large number of tools are validated for assessing stroke and there are well-established classification schemes for stroke such as Oxfordshire and TOAST (Trial of ORG 10172 in Acute Stroke Treatment) criteria.

Quality control

Employing a workforce in low density regions where strokes rarely occur creates problems. Each investigator will have to undertake standardised training in regard to history-taking and clinical examination. This can be partly addressed by using existing on-line training systems for instruments such as the 'National Institute of Health Stroke Scale'. Regular video-conference sessions will provide continuous feedback and training for rural researchers.

Close monitoring of data will be required to identify problems that may occur in rural areas. An online database has been designed which stores information directly on a central server, accessible wherever an internet connection exists. The connections can be encrypted and appropriately password-protected to meet privacy standards. A central server can use logs to check completeness of surveillance activities, store region-specific surveillance protocols, send reminder emails at critical follow-up times, and provide alerts if investigators in the field are not regularly entering surveillance information. Finally, we will assess ascertainment using advanced capture-recapture techniques.[8]

Managing a large remote workforce

Once the study commences, surveillance will be required year-round over two years. Using a student workforce will leave gaps during exam periods and holidays that will have to be filled. We will therefore recruit and train back-up staff from the health workforce in each rural region to cover such periods. Given the low population density, it may be possible to conduct some surveillance activities by telephone during emergency periods. Ultimately, if a region cannot be staffed, it will have to be discounted from the study.

Conclusion

Planning a population-based stroke study meeting the established criteria requires complex collaborations between researchers and institutions, crossing many clinical boundaries, and is filled with many potential pitfalls. Whilst ambitious, if successful, SEARCH will provide vital information comparing stroke in urban and rural Australia.

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