The Importance of Epidemiological Studies Should Not Be Downplayed

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Epidemiology as the study of distribution and determinants of disease frequency in human populations can and should be considered a basic science in medicine. Indeed, epidemiological principles and methods (including methods of statistical analysis) form the basis of any medical research, from case reports and other descriptive studies to cohort studies and experimental clinical trials. A randomized controlled trial is no more than a cohort study in which the investigator(s) allocate the exposure being studied to the participants in a random manner.

The advancement of medical knowledge follows a process resulting in a “spectrum of evidence.” Medical hypotheses are generated at the lowest level of evidence, where either clinical observations are made in a case-series or associations are observed in ecologic studies. An ecologic study is defined as an association study where associations between exposures and outcomes are made at the group level (ie, without jointly measuring exposures and outcomes in the same individuals). For example, it has been noted that individuals living in southern France and Italy have a unique diet (exposure), and also that they tend to have low rates of stroke and heart disease (outcome), suggesting a potential association of the diet and cardiovascular risk. Observations from these domains are considered weakest because of the lack of comparison groups in case-series and because multiple alternative pathways that can account for ecologic associations. The next level of evidence is considered the observational epidemiological studies that are generally classified as being (1) case-control, (2) cross-sectional, or (3) longitudinal cohort, and for a variety of reasons there is also considered to be a spectrum of increasing evidence as one moves from the case-control to the cross-sectional, and again when one moves from the cross-sectional to the longitudinal cohort study. All of these study designs increase the level of evidence by measuring exposures and outcomes in the same individuals, but are subject to the introduction (or obviation) potential of spurious relationships through confounding factors. Finally, the randomized clinical trial is considered the “gold standard” of evidence, largely because of protection from the impact of known or unknown confounding factors through the process of randomization.

Recognition of this increasing spectrum of evidence is important for 2 reasons. First, the evidence to support proposing a randomized trial is specifically provided by the earlier steps in the spectrum. One does not propose a trial without solid and convincing observational data, and one does not propose an observational study without solid and convincing ecologic or case-series data. The development of evidence is a process that has to be supported at all levels. In addition, most of the decisions in medical care are made on the basis of evidence that has not progressed to the level of randomized trials. This situation results from 2 observations: (1) randomized trials are remarkably expensive, and it is fiscally impossible to mount a trial to address the need for each class of information, and (2) the level of evidence is sometimes so strong that mounting a trial is considered unethical. Extreme examples of this latter observation are that there will never be a randomized trial of the harmful effects of smoking (requiring randomization of children to be smokers or nonsmokers), or the beneficial effect of parachutes (randomization to leaving airplanes with and without a parachute), or protective benefit of seat belts (randomization so that some cars will and will not have seat belts). An appreciation of this spectrum of evidence is important to both understand how a question advances to ever-higher levels of evidence, and how most medical decisions are made at lower levels of evidence.

Despite this, there is a recent worrisome trend to downplay the importance of epidemiological studies, especially nonexperimental epidemiological studies. Some academicians and medical research funding institutions tend to consider nonexperimental epidemiological studies as a ‘cold’ nonexciting research and indicate their preferences for clinical trials. Yet, as noted above there are a number of practical and theoretical issues in medicine that can only be answered by nonexperimental epidemiological studies, and experimental studies cannot be mounted without peer-reviewed and published evidence from the observational studies.

In addition to the important roles of descriptive epidemiological studies (case reports, case series, surveys, ecological studies) in the generation of etiological hypothesis, they also provide for the description of the frequency and/or patterns of disease occurrence at the individual or societal levels. Population-based surveys are crucial for quantifying the disease burden, contributing to evidence-based healthcare planning, and evaluating effectiveness and relative contribution of various primary and secondary/tertiary preventative measures for reducing burden of the disease/condition. In addition, analytic nonexperimental epidemiological studies

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often offer the only feasible alternatives to address specific hypotheses, such as the critically important role of case-control studies to test etiologic hypotheses in rare diseases. Whereas clinical trials can be mounted to study rare diseases, studies of primary prevention are impeded by required sample size to establish end points, and secondary prevention studies are impeded by difficulties in recruitment. At best, the number of questions that can be addressed through clinical trials of rare diseases is limited by the worldwide availability of patients. Hence, although properly designed randomized controlled trials remain the gold standard for testing cause-effect associations, there are a number of instances when such associations can only be tested in nonexperimental studies because of practical or ethical concerns. Thus, descriptive and analytical epidemiological studies are interrelated and complement each other, and the choice of a particular study design should not be based on the ‘individual’ or funding agency preferences but rather on the methodological, ethical and practical appropriateness of a particular epidemiological study design.

In the recognition of importance of epidemiological studies in stroke, a Section of Population Studies has been recently formed in the Stroke journal. As newly appointed Editors of this Section we would like to encourage researchers from all over the world to submit good quality papers on stroke epidemiology to our world-leading stroke journal. We would also like to take this opportunity to reinforce the importance of epidemiological studies in stroke and to call on funding research organizations to increase their funding support for these studies. Efforts should be made to ensure new good quality epidemiological studies in stroke in various countries and populations, including continuation of good quality ongoing stroke surveillance studies. We, together with other members of the Stroke Editorial team, are committed to ensure fast and objective peer-reviewing of all submitted manuscripts to ensure timely publication of manuscripts that meet Stroke journal acceptance criteria.

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None.

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