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Review Article

How to plan a good case–control study?

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ABSTRACT

Case–control studies are a very frequently used restudy design in clinical and epidemiological research. They are popular because they are easy, quick and inexpensive to plan and conduct. Despite the risk of several types of biases (selection bias, recall and measurement bias, and confounding), their results are often fairly robust. This article explains the basic steps in the design and conduct of case–control studies, and also explains their usual pitfalls, from the perspective of a clinical researcher.

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Research is an integral part of all branches of medicine. The excellent medical care available today has been possible only because several researchers, both clinicians and basic scientists, have spent several years conducting studies to define and differentiate between various disease conditions, to understand their pathogenesis and natural history, and tested methods to prevent and treat these diseases.

1. Types of research studies: observational versus interventional

Research studies are primarily of two types: observational and interventional. In the *observational studies*, an investigator merely observes the events that are happening to study subjects, without intervening in any manner with their natural course. Thus, he observes what happens to certain outcomes under different exposure conditions, which are not determined by him. He can choose what exposures and outcome to study, but cannot influence these. Thus, he is

akin to a keen bystander who faithfully records events as these happen.

In comparison, in *interventional studies*, the study subjects, either a subset or all of them, undergo an intervention which is determined by the investigator. The interventions can be varied and could include a drug, an endoscopic procedure, surgery, a lifestyle change and, at times, merely counselling or education. The investigator controls not only who gets the intervention (and who does not), but also its nature, timing, and dose or intensity. Thus, he is more than a bystander, and is in fact a ‘manipulator’. A typical example of an interventional study is a drug trial which was discussed in the previous issue of this journal.¹

2. Observational studies: types

Most of the observational studies focus on the relationship of an exposure (or health determinant) and an outcome (or endpoint). The meaning of an exposure and an outcome may

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vary from one study to another, even within the same subject field. For instance, in a study to understand the causation of rheumatoid arthritis (an outcome), smoking could be one of the risk factors (or exposures) studied. In turn, however, if the question is why some persons smoke whereas others do not, smoking would be an outcome, and factors such as age, gender, occupation, income, marital status, etc would be the determinants (or exposures) studied.

Observational studies can be classified broadly into four types:

- a. Cross-sectional studies
- b. Case-control studies
- c. Cohort studies
- d. Ecological studies

In a case-control study, the outcome of each subject is already known to the investigator at the start of the study, and the subjects are traced back to determine whether they had the particular exposure of interest in the past or not. In this sense, a case-control study is, by definition, retrospective.

In contrast, in a cohort study, subjects are enrolled based on the knowledge of their exposure status, and are then followed up to determine whether they go on to develop the outcome of interest or not. Thus, these studies are prospective in nature.

In cross-sectional studies, members of a population are queried at one point in time or over a short period for the presence of health outcomes as well as one or more exposures. This information is then used to explore the association between the exposure and outcome.

Ecological studies differ from the above three types of studies in having populations as the units of observation. These involve measurement of rates of an outcome and of one or more exposure in a series of populations (e.g. per capita alcohol consumption and rates of liver cirrhosis in several countries), and assessment of their relationship.

3. Case-control studies: definition

A case-control study compares a group of patients who have a particular disease or outcome of interest with another group of subjects who do not have this disease or outcome, and looks back retrospectively to compare how frequently the exposure to a particular risk factor had been present in each of these groups, and thereby determines whether there is a relationship between this risk factor and the particular disease (Fig. 1). If the exposure is found to be more frequent among cases than controls, one can infer that the outcome is associated with the particular exposure.² This is useful since it can be mathematically shown that if an exposure is N-fold more common among persons with a certain outcome, then conversely the outcome must also be N-fold more common among persons with exposure.

4. Advantages and disadvantages

Case-control studies are one of the commonest study designs. This is because these studies are quicker, simpler, cheaper and easier to design as well as conduct, compared to other study designs (Table 1).

Case-control studies are particularly apt for investigating disease outbreaks. These are also useful when studying rare diseases or outcomes. For instance, let us consider a situation where a few students residing in a boarding school have developed acute arthritis. The school authorities, the students and their parents expect a quick answer about what is causing these cases. In this setting, it would be best to interview the cases and a group of unaffected students (the controls) and obtain information on several exposures – e.g. age, gender, food items eaten, history of recent viral infections or gastrointestinal illnesses, a recent travel on a school trip, etc. This could quickly provide information on factors associated with

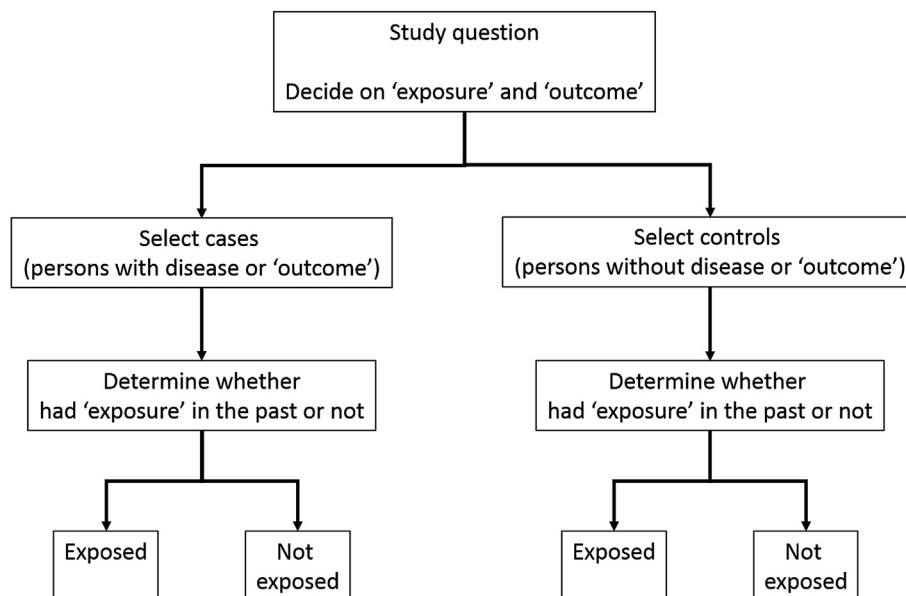


Fig. 1 – Steps in a case-control study.

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