Chapter 8 Cohort Study

Cohort study= Incidence Study = Longitudinal Study

Definition

Cohort means a group of the population who share similar characteristics. In clinical research, cohort study refers to the research design that examines the population at least at two points of the time. In the first point, we classify the population according to exposure to a certain risk factor into "exposed" or "not exposed" while in the second point of the time, we classify the population according to the development of the outcome to "positive" and "negative." Therefore, most of the cohort studies include a follow-up period to allow for the outcome to develop after exposure to a certain risk factor.

Examples

Ramchand, R., Ialongo, N. S., & Chilcoat, H. D. (2007). The effect of working for pay on adolescent tobacco use. American Journal of Public Health, 97(11), 2056-2062.

This study uses data collected from high school students from Baltimore, Maryland, and studies the differences in initiation of tobacco use between a cohort of adolescents that started working for pay and a cohort of adolescents that did not work. The results suggest that adolescents who work for pay have a higher risk of initiating tobacco use.

Nichol, K. L., Nordin, J. D., Nelson, D. B., Mullooly, J. P., & Hak, E. (2007). Effectiveness of influenza vaccine in the community-dwelling elderly. New England Journal of Medicine, 357(14), 1373-1381.

To determine the long-term effectiveness of influenza vaccines in elderly people, cohorts of vaccinated elderly and unvaccinated community-dwelling elderly were studied. The results suggest that the elderly who are vaccinated have a reduced risk of hospitalization for pneumonia or influenza.

Importance

Cohort studies are important to determine the association between exposure to a certain risk factor and developing an outcome (or a disease).

Types

→ Aetiological cohort study

Cohort studies that study the etiology of the disease by examining the hypothesis of whether exposure to a particular risk factor has led to the development of the disease of interest.

→ Non-etiological cohort study

Cohort studies that do not study the etiology of the disease but study the clinical outcome of exposure to a specific condition, treatment, or surgery. For example, a prospective cohort study assessing the impact of sofosbuvir antiviral treatment on the 12-week sustained virologic response of HCV patient. In this study, the investigators are following patients with HCV who are treated with sofosbuvir (exposed group) as well as those who are treated with the old traditional interferon based-treatment regimen (non-exposed group) and the two groups are compared after 3 months in terms of the sustained virologic response rate (the outcome of interest). This is an example of a prospective cohort study that does not investigate the etiology of the disease but rather, the response to treatment. In this example, we notice that the risk factor is the sofosbuvir treatment, and the outcome of interest is the virologic response.

Advantages

→ Stronger than case-control studies

Prospective cohort studies include a follow-up period. Therefore, this research design allows the investigators to constantly make sure that no other factors can interfere with the clinical outcome of the patient. Case-control studies lack the option of continuously monitoring the patients to ensure they are not exposed to other confounding variables because case-control studies are restricted by the available data in hospital records.

Disadvantages

→ More expensive

Cohort studies are expensive in time and in cost. The follow-up requires the investigators to keep in contact with the study participants for a long time. It is also important to keep the participants attached to the study as much as possible; therefore, investigators might offer financial incentives to keep the study going.

→ Time-consuming

The follow up of the patients can be time-consuming, especially if the outcome of interest takes several years to develop.

→ Lack of control over risk assignment

Like all observational study designs, cohort studies lack control over the assignment of certain individuals to an exposure. The investigators can not interfere with risk allocation. For example, in a prospective cohort study to determine the association between alcohol consumption and dementia, the investigators can not control which individuals become alcohol drinkers "exposed" and which individuals are not drinking alcohols "non-exposed." The participant allocation to risk factors occurs by nature independently from the study investigators.

→ Susceptible to bias by a differential loss to follow-up

There are several reasons for loss of the patients during the follow up as follows: (1) the patient is no longer willing to participate in the study, (2) the patient changed his residence setting and moved to another place, (3) the patient changes his contact information, (4) the patient condition deteriorated and is no longer capable on participation in the study, or (5) the patient died. Owing to the longitudinal nature of the cohort study, participants might drop out of the study over time, leading to a substantial bias due to incomplete patient data.

→ Confounding bias

See later (chapter of error and bias)

→ Zero-time bias

See later (chapter of error and bias)

→ Does not provide empirical evidence that is as strong as that offered by RCTs

The evidence provided by the cohort study is usually not as powerful as evidence provided by well-designed randomized controlled trials. The main reason for this difference is that cohort studies lack the control over risk assignment (the investigators can not control which participants are exposed to the risk factor). This is not the case in randomized controlled trials where the investigators allocate the study participants to the risk factor (study treatment) by themselves. In randomized controlled trials, the investigators have control over risk assignment, and they randomly allocate the study participants to the study groups (also called the treatment arms). This difference makes the randomized controlled trials being characterized by their high internal validity, and the evidence of well-designed RCTs is usually stronger than cohort studies. Further information about the methodology of clinical trials will be discussed in the chapter of clinical trials.

Example for the analysis of cohort study

A research team aimed to study the association between wound infection and burn. A group of individuals who underwent 2nd or 3rd-degree burn in the last two years was compared with another group who were not exposed to any burn in the last two years. Data of the study are summarized in the following table.

	Burned group	Non-burn group
With skin Infections	45	20
No skin infections	70	100

Incidence of skin infection among the burned group = 45/115=39.1%

Incidence of skin infection among the non-burned group = 20/120=16.6%

RR = 39.1/16.6=2.35

Interpretation of the RR: burned individuals have 2.35 higher risk of skin infection than non-burn individuals.