Introduction to epidemiology3 : study types; case-control, cohort, etc = 初歩の疫学3

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Introduction to epidemiology 3
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Intro to Epidemiology 3

Study Types; Case-Control, Cohort, etc.

Hi, everyone.　Today I will talk about types of epidemiologic research.

1. Time framework

To get an overview of the epidemiologic research, the key notion is　“the description and observation of disease/patient in a given time scale”.

Descriptive observations pertain to the “who, what, where and when of health-related state occurrence”.

However, to observe and describe health-related phenomena meaningfully, we need to be conscious of the time framework.　The following three are important;　time, directionality and timing.

1-1. Time

Time is a measure in which events can be ordered from the past through the present into the future,

1-2. Directionality

Directionality is the direction of inference of a study, from investigator’s viewpoint. The direction of a study refers to when the exposure is observed relative in time to when the outcome (health outcome) is observed.

In a study with forward directionality (forward-looking type study), the investigator starts by determining the exposure status of subjects.　This is the beginning, and there is not yet any outcomes.　Then, the investigator follows these subjects overtime to determine whether or not they develop the outcome.　Cohort studies and clinical trials have forward directionality.

In a study with backward directionality (backward-looking type study), outcomes　(diseases) are already there.　The investigator at first selects subjects with the outcome (cases, patients) and then selects subjects without outcomes (controls). When two groups of subjects are selected, then the investigator ask both groups of subjects about their previous exposures. Case-control studies have backward directionality.

In a study with non-directionality, the investigator put much value on the current observation and do not concern about direction (forward-looking or backward-looking).　This situation frequently happens when the investigator is occupied by accumulating current data and/or cases.　In this situation, neither variable (exposure, outcome) can be uniquely identified

as occurring first. The investigator observes both the exposure and the outcome simultaneously. This is the case of cross-sectional study.

1-3. Timing

Timing concerns whether the outcome has already occurred before the study actually began. If the outcome has occurred before the study is started, the timing is retrospective. If, on the other hand, the outcome occurs after the start of the study, then the timing is prospective. Clinical trials are always prospective.

2. Study design

There are four types of epidemiological study.

2-1. Case-series

Case-series is a collection of patients with common characteristics used to describe some aspect of a disease.
If you are health-care professional working in a clinic, and if you face some patients with similar unknown disease characteristic, you can compile the information of cases, and analyze them to learn about the disease. By doing so, you can improve your diagnosis, treatment, and also you will be able to formulate a new causal hypothesis.
If you are an officer working in a district health center, you can compile cases more systematically. When a case-series is complete for a defined geographical area, and if the area's population is known, this is the population-based surveillance.

2-2. Cross-sectional study

The cross-sectional study examines the relationship between disease (or health-related phenomena) and other variables of interest including exposure. A cross-sectional study reveals a snapshot of some outcome (disease, health-experience) of a population at a specific time. Doing the cross-sectional study is convenient and inexpensive. For a cross-sectional study, you need to identify some population you would like to describe, and then prepare questionnaire asking subjects characteristics (age, gender, etc.), outcome situation, exposure information and so on.

2-3. Case control study

The case-control study starts from cases (health-outcomes, subjects with the disease). Experiencing a single case (a subject with a disease of unknown etiology) is an initiation to know about the disease. Even if the disease is very rare, if you have chance to experience second and third cases, you will know more about the characteristic of disease. However, so long as you study only cases, you cannot go into the etiology (causal factor, exposure) of disease. In addition to cases, if you have controls (subjects without disease), you can approach to etiology by comparing cases and controls through asking the same question regarding previous exposures. This is case-control study.

In a case-control study, 600 lung cancer cases were identified. Controls were recruited to have the same gender and same age categories. After matching, 1200 controls were identified. In this study, the possible causes were scrutinized, such as "cigarette smoking". For 600 cases, 595 were smokers, and for 1200 controls, 1050 were smokers.

The case-control study focuses on cases, and it does not allow population-based direct risk estimation of exposures.

Because, case-control study work backwards from disease to exposure, and do not reveal population information. However, in a case-control study, we can calculate at first ODDS, and then ODDS RATIO, for the purpose of revealing relative largeness and/or smallness of risk.

To perform a calculation, we at first need to write down the numerical result of a case-control study by a two-way table.

		Exposure		
		Yes	No	
Outcome-	Yes	a (595)	b (5)	600
	No	c (1050)	d (150)	1200

ODDS is the ratio of the probability of occurrence of an event to that of nonoccurrence, or the ratio of the probability that something is one way to the probability that it is another way. (A Dictionary of Epidemiology, by Porta)

ODDS for “Outcome-Yes” is a/b (a divided by b), and
ODDS for “Outcome-No” is c/d (c divided by d).

For the example of lung cancer study,

the ODDS of smoking among cases is calculated as 595/5 = 119.00, and
the ODDS of smoking among controls is 1050/150 = 7.00.

Now, we have two ODDS, and then we can calculate ODDS RATIO.

ODDS RATIO is the ratio of two odds, as (a/b) divided by (c/d),

= ad/bc= (595*150)/(1050*5) = 17.00

Odds ratio can be larger than one, equal to one, or smaller than one. An odds ratio larger than one says the exposure odds for cases is larger than the exposure odds for controls.

Odds ratio of exposure can be used to estimate the incidence rate ratio.

2-4. Cohort study

A cohort is a group of people who share a common characteristic or experience within a defined period.

In a cohort study, you need preventive sense to focus at first on the exposure (hypothesized cause), preceding the occurrence of outcome (disease). In other words, a cohort study has forward directionality.

The core of cohort study is, to watch/observe large numbers of people (group or population) over a long period (years) along with the level of exposure, detect and accumulate outcomes (disease), and compare the occurrence of outcomes (by calculating incidence) among exposure level.

In a cohort study of walking to prevent coronary heart disease in women, 13,000 women with minimum walking (exposure-yes) and 14,000 women with normal walking (exposure-no) were recruited at the base-line survey in 1986,

and occurrence of coronary events were followed up until 1994.

During 8 years followup, 180 coronary events were detected for "exposure-yes", and 100 coronary events were detected for "exposure-no"

		Exposure	
		Yes	No
Outcome-	Yes	a (180)	b (100)
	No	c (12,820)	d (13,900)
		13,000	14,000

Cumulative incidence (CI) is calculated as follows.

CI = (# of new cases) / (# of disease-free subjects at baseline)

For minimum-walking: CI = 180/13,000 = 0.0138

For normal-walking: CI = 100/14,000 = 0.0071

In the real situation of cohort observation, the supposition that all persons are followed up exactly the same time period does not fully apply. To follow the reality, the notion of "person-time" is used.

Person-time is a measurement combining persons and time as the denominator in incidence. As individual subjects are at risk of developing the disease for varying periods, person-years is more accurately express basis to calculate incidence as follows.

PERSON-TIME INCIDENCE RATE (PTIR):

(# of events occurring during the interval) / (# of person-year units at risk observed during the interval)

For minimum-walking: PTIR= 180/98,800 = 0.0018

For normal-walking: PTIR= 100/105,000 = 0.0009

2-5. Trials/intervention studies

Trials are studies where an intervention designed to improve health has been applied to a population, and the outcome assessed at follow-up. Trials/interventions are performed in laboratories and clinical studies to establish beneficial effects of drugs or procedures. The trial/intervention study has, the similar design as a cohort study. The difference is that the exposure status of the study population is controlled by the investigator to observe how this affects the health status of subjects. Trials/intervention study is essentially an EXPERIMENT, and typical procedure follows "randomized controlled trial". I will talk about the details in another chance.

(Masaki Moriyama)