AN ANALYSIS ON ISSUES OF CONCERNS IN EPIDEMIOLOGICAL STUDY DESIGN

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Abstract:

Epidemiology is the analysis and study of the distribution, determinants, patterns and factors affecting the health and disease conditions in a distinct population. It is a foundation of public health, and helps in making policy decisions and evidence-based exercise by identifying risk factors for disease and aims for protective healthcare.

Objectives

To analyse the issues of concerns and review existing practice in the analysis and reporting of epidemiological research.

Design: Inspection of articles published in 2019 that investigated associations between distribution pattern of risk factors and exposure variables and disease incidences /measures in individuals.

Setting Eligible journals including all major epidemiological journals, all major general medical journals, and the two leading journals in cardiovascular disease and cancer.

Main outcome measures Every research paper was evaluated with in a standard format.

Results We found 96 articles in observational epidemiology; most were either cohort or case-control studies. Most studies looked at cancer and cardiovascular disease, even after we excluded specialty journals. Confidence intervals were reported in most studies (72), though use of P values was less common (38). Quantitative exposure variables predominated, which were mostly analysed as ordered categories but with little consistency or explanation regarding choice of categories. Sample selection, participant refusal, and data quality received insufficient attention in many articles. Statistical analyses commonly used odds ratios (43 articles) and hazard/rate ratios (21), with some inconsistent use of terminology. Few articles explained their choice of confounding variables; many performed subgroup analyses claiming an effect modifier, though interaction tests were rare. Several investigated multiple associations between exposure and outcome, increasing the likelihood of false positive claims. There was evidence of publication bias.

Conclusions This study raises concerns regarding inadequacies in the analysis and reporting of epidemiological publications in mainstream journals.

Key Words: Epidemiological factors, Study Design

1.Introduction

Observational epidemiology generates a plethora of publications across numerous epidemiological and medical journals. Many texts tackle the quality of epidemiological studies, but few directly focus on epidemiological publications. We reviewed the quality and methodological acceptability of research epidemiology published in 2019. We concentrated on analytical epidemiology—that is, studies that used observational data on people from the general population to quantify relations between exposures and disease.
Relationship of exposure with a disease or an outcome. As a first step, they define the hypothesis based on the research question and then decide which study design will be best suited to answer that question. How the researcher conducts the investigation is directed by the chosen study design. The study designs can be broadly classified as experimental or observational based on the approach used to assess whether exposure and an outcome are associated. In an experimental study design, researchers assign patients to intervention and control/comparison groups in an attempt to isolate the effects of the intervention. Being able to control various aspects of the experimental study design enables the researchers to identify causal links between interventions and outcomes of interest. In several instances, an experimental study design may not be feasible or suitable; observational studies are conducted in such situations. As the name indicates, observational studies involve merely observing the patients in a non-controlled environment without actually interfering or manipulating with other aspects of the study and therefore are non-experimental.

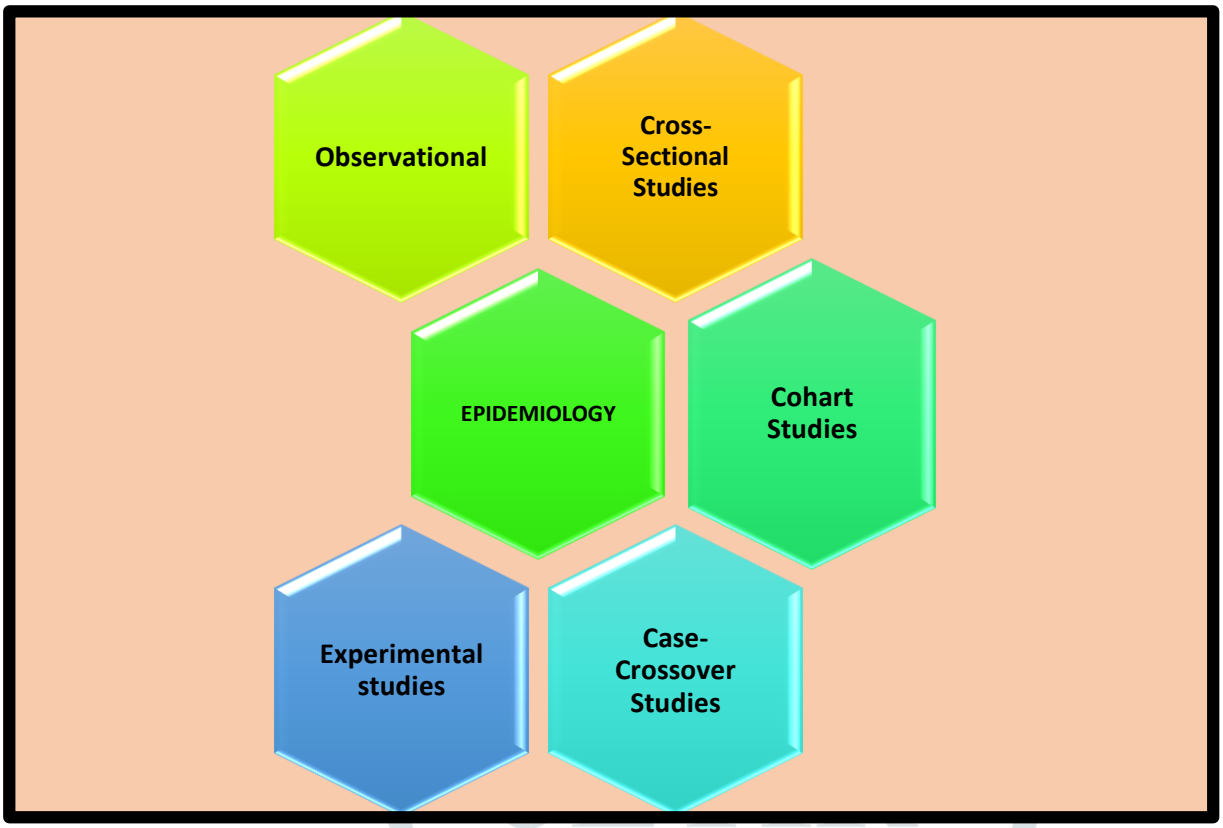

Fig. 1.1 Types of Epidemiological study design

1.1 Case-Control Studies

Case-control studies are used to determine the degree of associations between various risk factors and outcomes. The case-crossover design was developed to study the effects of transient, short-term exposures on the risk of acute events, such as myocardial infarction, in the early 1990s. This paper illustrates how the principles of case-crossover design are related to the principles of crossover and case-control designs and stipulates the possibilities of case-crossover design The factors that affect the risk of a disease are called exposures. Case-control studies can help identify beneficial or harmful exposures. As the name suggests, there are two groups of patient cases and controls in a case-control study. Cases are patients who have a particular disease, condition, or disability. Controls are those patients that do not have the disease.

Typically, researchers identify appropriate representative controls for the cases that they are studying from the general population. Then they retrospectively look in the past for the possible exposures these patients might have had to a risk factor. Selecting the patients for the control group is a very critical component of research based on case-control studies. Due to the retrospective nature of the study design, case-control studies are subject to recall bias. Case-control studies are inexpensive, efficient, and often less time-consuming to conduct. This study design is especially suitable for rare diseases that have long latency periods.

1.2 Case-Crossover Studies

Case-crossover studies are helpful to study triggers within an individual. When the researcher is studying a transient exposure or risk factor, the case-crossover design is useful. This is a relatively new study design where there is a case and a control component, both of which come from the same individual. Each case is self-matched by serving as its own control. Determining the control and case components period is a critical and difficult aspect of a case-crossover study.

1.3 Cohort Studies

Cohort studies initially classify patients into two groups based on their exposure status. Cohorts are followed over time to see who develops the disease in the exposed and non-exposed groups. Cohort studies can be retrospective or prospective. Incidence can be directly calculated from a cohort study as you begin with exposed and unexposed patients, unlike a case-control study where you start with diseased and non-diseased patients. Relative risk is the measure of effect for a cohort study. Cohort studies are subject to very low recall bias, and multiple outcomes can be studied simultaneously. One of the disadvantages of cohort studies is that they are more prone to selection bias. Studying rare diseases and outcomes that have long follow-up periods can be very expensive and time-consuming using cohort studies.

1.4 Cross-Sectional Studies

Cross-sectional studies are observational in nature and give a snapshot of the characteristics of study subjects in a single point of time. Unlike cohort studies, cross-sectional studies do not have a follow-up period and therefore are relatively simple to conduct. As the exposure status/outcome of interest information is collected in a single moment in time, often by surveys, cross-sectional study design cannot provide a cause-effect relationship and is the weakest of the observational designs. This study design is generally used to assess the prevalence of a disease in a population.

1.5 Ecological Studies

Ecological studies are used when data at an individual level is unavailable, or large-scale comparisons are needed to study the population-level effect of exposures on a disease condition. Therefore, ecological study results are applicable only at the population level. The types of measures in ecological studies are aggregates of individual-level data. These studies, therefore, are subject to a type of confounding called an ecological fallacy, which occurs when relationships identified at group level data are assumed to be true for individuals. Ecological studies are generally used in public health research.

1.6 Experimental Studies

Randomized Clinical Trials

Randomized clinical trials or randomized control trials (RCT) are considered the gold standard of study design. In an RCT, the researcher randomly assigns the subjects to a control group and an experimental group. Randomization in RCT avoids confounding and minimizes selection bias. This enables the researcher to have similar experimental and control groups, thereby enabling them to isolate the effect of an intervention. The experimental group gets the exposure/treatment, which can be an agent involved in causation, prevention, or treatment of a disease.

2. Output of study

The control group receives no treatment, a placebo treatment, or another standard of care treatment depending on the study's objective. The groups are then followed prospectively to see who develops the outcome of interest. RCT's are expensive, and researchers using this study design often face issues with the integrity of randomization due to refusals, drops outs, crossovers, and non-compliance.

3.Issues of Concern

Study design should be well thought of before initiating a research investigation. Choosing an inappropriate study design may undermine overall study validity. Critical thinking about the possible study design issues beforehand will ensure that the research question is adequately addressed.Errors in study design are extremely difficult to correct after study completion. Thorough planning is required to avoid weak conclusions or unconvincing results.

4.Increased Healthcare team Consequence

All interprofessional healthcare team members, including clinicians, mid-level practitioners, nurses, pharmacists, and therapists, need to be well-versed in the various study designs utilized to perform medical research. Such knowledge can help delineate strong studies and results from weaker ones, determine the clinical applicability of study results, and enhance patient care through the appropriate application of data-driven research results. Failure to understand study design and the strength of data provided by various types of studies can lead to improper decision-making and negatively impact patient outcomes.

5. Clinical Significance

Study design plays a major role in determining the scientific value of a research study. Understanding the basic study design concepts will aid the clinicians in practicing evidence-based medicine. Case-crossover design is amenable for studying the effects of varying short-term air pollution exposure on health outcomes with an abrupt onset, such as myocardial infarction or asthma attack.

6. Statistical Analysis: Despite the enormous variety of epidemiologic problems and statistical solutions, there are two basic approaches to statistical analysis: regression and non-regression methods. A regression is a statistical technique that relates a dependent variable to one or more independent (explanatory) variables. A regression model is able to show whether changes observed in the dependent variable are associated with changes in one or more of the explanatory variables.

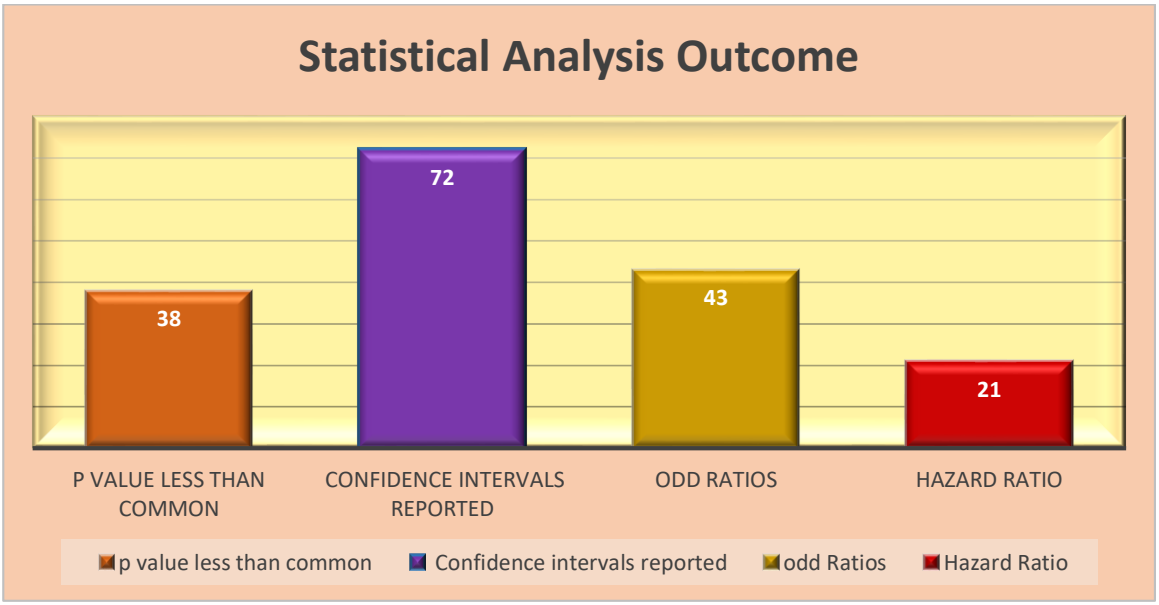

Fig. 6.1 Statistical analysis outcome

7.Result and Conclusions : Important frequency measures in cohort studies are incidence and mortality. Important effect measures such as the relative risk (RR), hazard ratio (HR), standardized incidence ratio (SIR), standardized mortality ratio (SMR), and odds ratio (OR) calculated. In case-control or cross-sectional studies, the OR calculated for various papers as an effect measure. In cross-sectional studies, prevalence is the most important frequency measure. The interpretation of different frequency measures .This study raises concerns regarding inadequacies in the analysis and reporting of epidemiological publications in mainstream journals.

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