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Review article

Research and publish. Part 5. How to present and evaluate an observational study: cohorts

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Abstract

Introduction: Cohort studies are a fundamental design in epidemiological and clinical research, allowing the evaluation of associations between exposures and health outcomes over time. Their longitudinal structure enables the estimation of disease incidence and the calculation of association measures such as relative risk. However, these studies present methodological challenges, including selection bias, information bias, and confounding, which must be addressed through appropriate design and analytical strategies. **Methods:** To enhance the quality and transparency in reporting cohort studies, the STROBE Statement provides a detailed guide on key aspects to include in a scientific article, such as participant selection, exposure and outcome measurement, and statistical methods used. **Results:** In the interpretation of cohort studies, the JAMA Evidence framework facilitates the assessment of study validity through a three-step approach: identification of bias risk, analysis of the magnitude and precision of the association, and determination of the applicability of findings in clinical practice. **Conclusion:** Cohort studies are essential for generating health-related evidence, but their validity relies on rigorous execution and proper critical appraisal. The use of tools such as STROBE and JAMA Evidence improves the quality of reporting and interpretation, strengthening their impact on biomedical research and clinical practice.

Keywords

Cohort, epidemiology, observational studies, relative risk, validity (epidemiology), evidence-based medicine.

INTRODUCTION

Cohort studies are a key design in epidemiological and clinical research, used to evaluate the relationship between exposures and health outcomes. Their main characteristic is the longitudinal follow-up of a group of individuals, which allows for the estimation of disease incidence and the assessment of its relationship with specific risk factors[(1)]. Unlike cross-sectional studies, which only allow the evaluation of prevalences at a single point in time, cohort studies can determine if an exposure precedes the outcome and estimate the relative risk[(2)].

Types of cohort studies

Cohort studies can be classified based on the timing of exposure measurement and the structure of the study population.

Prospective cohort studies

In this design, researchers identify and select participants before the outcome of interest occurs. Exposed and non-exposed groups are defined and followed over time to assess the incidence of the disease. A key advantage is the ability to measure exposures accurately and establish the

temporal sequence between exposure and disease, which reduces information bias[1].

A classic example is the Framingham study. It was one of the most influential cohort studies in cardiovascular epidemiology, initiated in 1948 in Framingham, Massachusetts. Key risk factors for cardiovascular diseases, such as smoking, hypertension, and dyslipidemia, were identified[1,3].

Retrospective cohort studies

In this design, both the exposure and the outcome have already occurred by the time the study begins. Medical records, databases, or clinical histories are used to reconstruct the exposure history and assess the incidence of the disease. While this method is more time- and cost-efficient, it can be limited by the quality of available data and information bias[1].

An example is exposure to radiation and cancer. Retrospective studies in Hiroshima and Nagasaki have evaluated the incidence of cancer among atomic bomb survivors, using historical records to determine exposure and follow individuals over the years[1,4].

Ambispective cohort studies

This design combines both prospective and retrospective elements, using historical data to assess past exposures and continuing to follow individuals in the present and future. This approach allows for the use of prior information, which can be complemented with prospective data.

An example is the British birth cohort of 1946. This study began with perinatal data and has followed participants into adulthood, gathering information on multiple exposures throughout their lives[1].

Special cohort studies

There are methodological variations that can enhance the efficiency and precision of cohort studies.

- *Multiple cohort studies*: These studies compare two or more groups of individuals with different levels of exposure. For example, workers exposed to a chemical agent can be compared to unexposed workers in the same industry[1]. One example is the study on asbestos exposure. A study compared workers exposed to asbestos with office employees and evaluated the incidence of mesothelioma[1].
- *Matched cohort studies*: In this design, each exposed participant is matched with an unexposed individual with similar characteristics, such as age and sex, reducing the effect of confounding variables[1]. One example is studies on smoking and lung cancer. Several studies have matched smokers and non-smokers based on factors such as age and socioeconomic status, improving comparability between the groups[1].
- *Nested cohort studies*: These studies combine the advantages of cohort and case-control studies. Within an established cohort, cases of the disease are identified and compared with a randomly selected subset of controls from the same cohort, reducing costs and improving study efficiency[1]. An example is the *Nurses' Health Study*. This study has used a nested cohort design to investigate risk factors for breast cancer and other chronic diseases, leveraging its extensive prospective database[5].

Advantages and disadvantages of cohort studies

Despite their benefits, cohort studies present methodological challenges that should be considered (**Table 1**).

Table 1. Advantages and disadvantages of cohort studies

Advantages	Disadvantages
They allow to evaluate incidence and relative risk	They are expensive and require long follow-up periods
They establish the temporal sequence between exposure and disease	There may be loss to follow-up of participants
They avoid memory biases common in retrospective studies	They may require large sample sizes
They allow the study of multiple outcomes from a single exposure	Exposure to confounding factors that are difficult to control

Adapted from: Gordis L. Elsevier; 2013[1].

Main biases in cohort studies

Cohort studies can be subject to biases that affect the validity of their results, including the following:

- Selection bias: This occurs if the comparison groups are not representative or if there are systematic differences in the inclusion of participants[1].
- Information bias: This arises when the measurement of exposure or outcome is inaccurate. It is especially relevant in retrospective studies that rely on previous records[1].
- Confounding: This happens when an external variable is associated with both the exposure and the outcome, thus biasing the observed association[1].

Cohort studies have been fundamental in epidemiology and clinical research, as they provide crucial information on risk factors and preventive strategies in public health. Their implementation requires rigorous design to minimize biases and maximize the validity of findings. The choice between a prospective, retrospective, or nested design

depends on the study's objectives, the availability of data, and the resources available. Despite their challenges, the impact of these studies on risk identification and the formulation of public health policies is undeniable[1].

METHODS

Presentation of a cohort study according to *STROBE*

The *STROBE Statement* (Strengthening the Reporting of Observational Studies in Epidemiology) is an international guideline designed to improve the quality and transparency in the presentation of observational studies, including cohort studies[6]. Its goal is to ensure that authors provide sufficient information for readers to assess the validity of the findings, minimizing biases and promoting reproducibility.

Key elements of *STROBE* in a cohort study

STROBE includes 22 items, several of which are essential for the methods section of a scientific article. Below are the most relevant points for a cohort study.

Study design

- Explicitly state that it is a cohort study and specify whether it is prospective, retrospective, or ambispective.
- Justify the choice of design based on the research question.
- Describe the hypothesis and the expected direction of the association.

Example of phrasing: "A prospective cohort study was conducted to evaluate the relationship between benzodiazepine exposure and the risk of falls in older adults, with a five-year follow-up."

Selection of participants

- Inclusion and exclusion criteria: clearly define the criteria used to select participants.
- Recruitment methods: indicate whether participants were identified from medical records, surveys or population sampling.
- Define the source of the cohort: explain whether it comes from a hospital database, epidemiological database or pre-existing cohort.

Example: "Patients aged ≥65 years treated in healthcare centers affiliated with the National Health System between 2015 and 2020 were included. Patients with prior history of fractures or neuromuscular disease were excluded."

Definition of exposure and outcome

- Exposure measurement: describe how exposure was determined (clinical history, self-report, biomarkers, etc.).
- Outcome measurement: explain how the diagnosis or event of interest was established (radiological confirmation, laboratory tests, among others).
- Covariates and confounding: explain how confounding factors were addressed through matching, stratification, or statistical models.

Example: "The primary outcome was the incidence of severe falls, defined as those requiring hospitalization. Benzodiazepine exposure was defined as continuous use for ≥3 months according to the electronic medical record."

Bias minimization

STROBE recommends documenting strategies to minimize the following biases:

- Selection bias: use of propensity score matching or strict inclusion criteria.
- Information bias: application of standardized methods to measure exposure and outcome.
- Confounding: adjustment by multivariate models or sensitivity analysis.

Example: "to minimize confounding bias, the analysis was adjusted for age, sex, comorbidities, and polypharmacy using a Cox regression model."

Sample size and statistical power

- Explain the calculation of the sample size based on the expected incidence of the outcome and the minimum detectable effect.
- Justify whether the sample is sufficient to detect statistically significant differences.

Example: "the sample size calculation determined that 8000 participants were required to detect a 20% difference in the risk of falling with a power of 80% and a significance level of 5%."

Statistical methods

- Specify the methods used to analyze the data.
- Indicate how missing data were handled.
- Include the measures of association used, such as risk ratio (RR), hazard ratio (HR) or odds ratio (OR).

Example: "a Cox regression model was used to estimate the adjusted hazard ratio, and a sensitivity analysis assessed the impact of missing data."

RESULTS

Critical appraisal of a cohort study according to *JAMA Evidence*

To properly interpret the results of a cohort study, the *JAMA Evidence* guide, which proposes a three-step structured approach, should be applied[7].

Step 1: Bias risk assessment

The first step is to determine whether the study minimized biases that could affect internal validity.

Comparability of the groups:

- Did the groups start with the same risk of outcome?
- Were initial differences adjusted by statistical models?
- Were known confounding factors controlled for?

Example: "the benzodiazepine-exposed group had more comorbidities than the non-exposed group, so a propensity score adjustment was made."

Evaluation of the outcome:

- Were the same methods used to assess outcome in both groups?
- Was there a risk of surveillance bias?

Example: "the outcome was determined by standardized hospital diagnoses, minimizing information bias."

Complete follow-up:

- Was the loss rate less than 20%?
- Were there differences in follow-up between the groups?

Example: "the follow-up rate was 95% in both groups, which reduced the impact of loss-to-follow-up bias."

Step 2: Assessment of the magnitude and precision of the association

The second step is to assess the magnitude and precision of the association between exposure and outcome.

Magnitude or strength of the association:

- Measures such as relative risk (RR), hazard ratio (HR) or odds ratio (OR) are reported.
- RR values close to 1 indicate a weak association, whereas values >2 suggest a stronger relationship.

Example: "prolonged use of benzodiazepines was associated with an increased risk of falls (adjusted HR: 1.52; 95% CI: 1.32-1.75)."

Estimation accuracy:

- It is evaluated by observing the confidence intervals (95% CI).
- A wide CI suggests uncertainty, while a narrow CI indicates greater precision.

Example: "the 95% CI did not include unity, indicating that the association is statistically significant".

Step 3: Clinical applicability

The third step is to determine whether the findings can be applied in medical practice.

Comparability with the clinical population:

- Are participants representative of patients in clinical practice?

Example: "the study included only hospitalized elderly adults, which limits the generalizability to outpatient populations."

Follow-up duration:

- Was it enough to capture the outcome?

Example: "the mean follow-up was 6.2 years, which made it possible to evaluate long-term effects."

Magnitude of absolute risk:

- The absolute risk is compared between groups.

Example: "the absolute risk of falls in benzodiazepine users was 12.3%, compared with 8.5% in the control group (number needed to treat [NNT]): 25)."

CONCLUSION

Cohort studies are essential in epidemiological and clinical research as they allow for the evaluation of the relationship between exposures and outcomes over time. Their longitudinal design enables the estimation of disease incidence and the calculation of relative risk, which contributes to the identification of risk factors and public health prevention strategies.

To ensure proper presentation in scientific publications, the *STROBE Statement* provides a structured framework that promotes transparency and reproducibility in studies. Additionally, critical evaluation based on *JAMA Evidence* allows for the assessment of the internal and external validity of findings through an analysis of bias risk, the magnitude of the association, and clinical applicability.

In conclusion, the proper implementation, presentation, and evaluation of cohort studies are key to ensuring their validity and utility in health decision-making. The use of methodological checklists such as *STROBE* and *JAMA Evidence* strengthens the rigor of these studies and guarantees their impact on biomedical research and clinical practice.

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