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RESEARCH AND SURGERY

Classification of studies that apply to the area of surgery

Clasificación de los estudios que aplican al área de cirugía

Mónica Bejarano, MD, MSc, MACC[1],
Patrizio Petrone, MD, PhD, MPH, MHSA, FACS, MSCGP (Hon), MAAC, MACC[2]

1 Editor, Revista Colombiana de Cirugía; Department of Surgery, Fundación Valle del Lili. Cali, Colombia.
2 Co-editor, Revista Colombiana de Cirugía; NYU Grossman Long Island School of Medicine. Mineola, New York, USA.

Abstract

Introduction. Clinical research provides us with tools to develop projects in which our activity in the professional field is shown but requires an appropriate methodology that follows the guidelines of the scientific method. One of the basic questions at the beginning of a research project is to carry out an appropriate design for each type of study proposed.

Methods. A review of the available literature was performed and the most relevant aspects related to the types of studies that apply to the area of surgery are presented in a narrative form.

Results. Depending on the relationship between the time in which the study is done and the facts evaluated, studies can be prospective or retrospective. From the point of view of temporality, they can be longitudinal or transversal. Depending on the unit of analysis, studies can be focused on the level of individuals or populations. Seen from the intervention, epidemiological studies may or may not have an experimental design.

Conclusion. Controlled clinical trials are considered the gold standard of research designs because they provide the most convincing evidence of the relationship between exposure and outcome. However, in the area of surgery, performing experimental studies is not easy because they face serious ethical problems and greater risks of bias. Therefore, it is necessary to know other types of studies that apply.

Keywords: research and development projects; scientific research and technological development; research design; epidemiology and biostatistics; epidemiologic study characteristics; general surgery.

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Corresponding author: Mónica Bejarano, Carrera 59 # 11B-56, Cali, Colombia. Tel.: +57 3155574039. E-mail: monicirugia@gmail.com
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Resumen

Introducción. La investigación clínica nos provee de herramientas para desarrollar proyectos en los cuales se muestre nuestra actividad en el campo profesional, pero requiere de una apropiada metodología, que siga los lineamientos del método científico. Una de las cuestiones básicas en el inicio de un proyecto de investigación es realizar un diseño adecuado para cada tipo de estudio propuesto.

Métodos. Se hizo una revisión de la literatura disponible y se presenta de forma narrativa los aspectos más relevantes relacionados con los tipos de estudios que aplican al área de cirugía.

Resultados. Según la relación entre el momento en que se realiza el estudio y los hechos evaluados, los estudios pueden ser prospectivos o retrospectivos. Desde el punto de vista de la temporalidad, pueden ser longitudinales o transversales. De acuerdo con la unidad de análisis, los estudios se pueden enfocar a nivel de los individuos o de las poblaciones. Vistos desde la intervención, los estudios epidemiológicos pueden tener un diseño experimental o no.

Conclusión. Los ensayos clínicos controlados son considerados el "estándar de oro" de los diseños de investigación porque proporcionan la evidencia más convincente de la relación entre exposición y resultado. Sin embargo, en el área de cirugía, la ejecución de estudios experimentales no es fácil porque se enfrentan a serios problemas éticos y mayores riesgos de sesgos. Por eso, es necesario conocer otros tipos de estudios que aplican.

Palabras clave: proyectos de investigación y desarrollo; investigación científica y desarrollo tecnológico; proyectos de investigación; epidemiología y bioestadística; características de estudios epidemiológicos; cirugía general.

Introduction

The progressive introduction of the experimental method in current medicine has led us to find ourselves facing an increasingly scientific medicine. Clinical research provides us with tools to develop projects in which our activity in the professional field is sampled but requires an appropriate methodology that follows the guidelines of the scientific method. In this way, the deductive method can be applied (from the general to the particular), or the inductive method (from the parts to the whole). The formal sciences (mathematics) apply the first method, while the factual sciences (physics, chemistry, medicine) apply the second [1].

On the other hand, epidemiological (clinical research) and basic (laboratory experimental) are considered two major fields of research. In turn, clinical research is divided into basic and applied research. While basic research acquires new knowledge, applied research specifically solves clinical problems. Finally, both have an experimental research component (which is carried out on animals) and a clinical research component (which is carried out on patients) [2]. In order to unify these definitions, what is known as translational research has emerged, as an attempt to transfer new information acquired in the laboratory to daily clinical practice [1].

Types of epidemiological studies in surgery

There are several types of epidemiological studies that apply to the area of surgery. First, if you look at the relationship between the moment in which the study is carried out and the facts evaluated, the studies can be prospective or retrospective. A prospective study is one that begins before the exposure (or the "risk factor" that may cause the disease or condition) and outcome occur, while a retrospective study is one that begins after the exposure (and likely the outcome) has been determined (Figure 1).

Second, it must be understood that these studies, from the point of view of temporality, can be longitudinal when data are collected from the same sample repeatedly over a long period of time, or cross-sectional, when data are collected

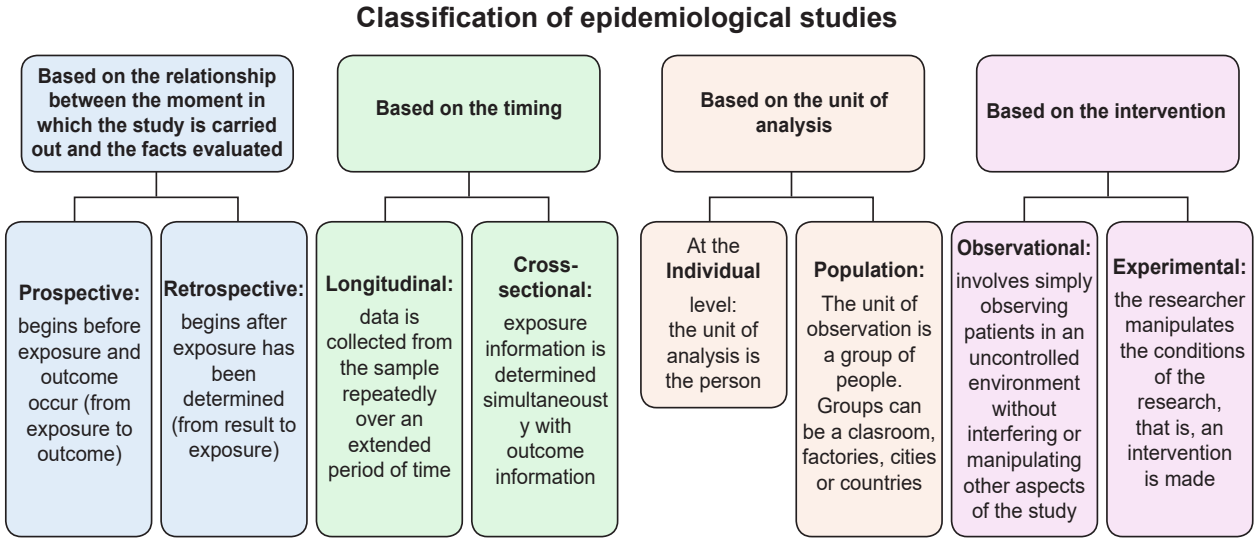


Figure 1. Classification of epidemiological studies.
Source: Created by the authors.

at a single point in time. The third thing is to be aware that, according to the unit of analysis, studies can be focused on the level of individuals or populations.

Fourth, seen from the intervention, epidemiological studies may or may not have an experimental design (Figure 2). In common language, an experiment refers to any trial or test, but for many scientists, the term has a more specific meaning: "an experiment is a set of observations, made under controlled circumstances, in which the scientist manipulates the conditions to determine what effect the manipulation has on the observations." However, for epidemiologists, the word experiment usually connotes that the researcher manipulates the conditions of the research, that is, makes an intervention, whether therapeutic or preventive [3].

Among experimental studies, controlled clinical trials are considered the "gold standard" of research designs because they provide the most convincing evidence of the relationship between exposure and outcome. Only randomized control trials can meet the criteria for causal inference, which means establishing a cause-and-effect relationship.

Sir Austin Bradford Hill, an English statistician, proposed nine causality criteria in 1965 that, although partly questioned, continue to be accepted today [4]. They include:

1. Temporal relationship
2. Strength of association
3. Biological plausibility
4. Dose-response relationship
5. Replication of findings
6. Effect of removing exposure
7. Alternative explanations considered
8. Specificity of the association
9. Coherence with other knowledge

Prospective clinical studies, which include longitudinal randomized clinical trials, are the ideal studies to evaluate a treatment, which is why it is recommended to have a control group to compare the results of the treatment [5]. However, in the area of surgery, its execution is not easy because they face serious ethical problems and greater risks of bias.

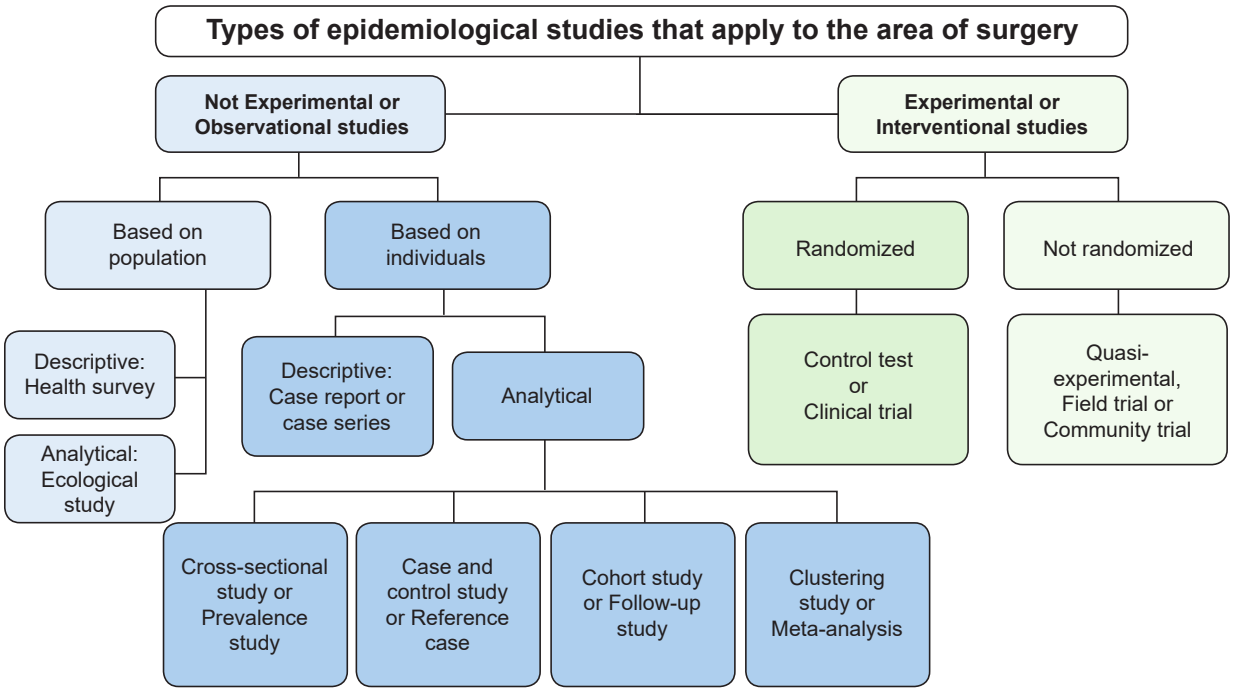


Figure 2. Types of epidemiological studies.
Source: Created by the authors.

On the left side of figure 2 are the non-experimental studies, which are known as observational. By definition, in these studies the researcher does not assign or alter the exposure being evaluated. They are divided into descriptive or analytical. Descriptive studies are used to "describe" exposure and disease in a population and can be used to generate hypotheses but are not designed to test a hypothesis. Analytical studies are designed to evaluate the association between exposure and a disease or other health outcome and therefore could test hypotheses.

The classification into descriptive and analytical observational studies does not require that the study design be retrospective. For example, a cohort study is retrospective if the exposure and disease are already present when the study begins, but it may be prospective if the disease has not been diagnosed when the study begins, although the exposure may have occurred, so follow-up over time is needed, which depends on the pathophysiology of the entity being investigated. While a cross-sectional study is one in which the exposure and the result are determined at the same time, which is why, in this type of study, no temporality between the variables or causality relationship can be inferred.

Retrospective studies include narrative reviews and systematic reviews, which collect and analyze published information in a structured and explicit way. There are two types, qualitative, which present the evidence in a descriptive form, without statistical analysis, and quantitative (or meta-analysis), which combine results using statistical techniques[6].

Meta-analysis is a systematic approach to identify, evaluate, synthesize or combine the results of relevant studies, through the statistical analysis of a series of data, estimating a new parameter that synthesizes what has been contributed by each of the individual investigations[7,8]. Its objective is to achieve a larger sample size to obtain information of greater statistical significance.

Depending on the type and objective of an investigation, the method selected to obtain the data can be in three different ways [9,10]: observation, measurement or formulation of a hypothesis (Table 1). One of the basic questions in epidemiology and at the beginning of a research project is to carry out an appropriate design for each type of study proposed. Regardless of the experience the researcher has, it is recommended to follow the guidelines published for each one, which can be consulted on the EQUATOR network (Enhancing the QUAlity and Transparency Of health Research), available at https://www.equator-network.org/. Table 2 summarizes the guidelines

Table 1. Types of research studies, objectives and design.

Research	Objective	Ideal design
Therapeutic	Efficacy of a new treatment or surgery	Controlled and randomized trial
Diagnosis	Validity of a new diagnosis or examination	Cross-sectional study
Screening	Validity of a diagnosis in a large population	Cross-sectional study
Prognosis	Detection of aspects of a disease	Longitudinal cohort study
Risk factors	Determine its relationship with the development of a disease	Cohort or case-control study

Source: Created by the authors.

Table 2. Guidelines for the main types of studies in the area of surgery.

Study type	Guide for the presentation of scientific reports or articles	Available at
Case report	The CARE guidelines: Consensus-based clinical case reporting guideline development. Gagnier JJ, Kienle G, Altman DG, Moher D, Sox H, Riley D; CARE Group.	BMJ Case Rep. 2013;2013:bcr2013201554. https://doi.org/10.1136/bcr-2013-201554
Observational studies	The Strengthening the Reporting of Observational Studies in Epidemiology (STROBE) Statement: Guidelines for reporting observational studies. von Elm E, Altman DG, Egger M, Pocock SJ, Gotzsche PC, Vandenbroucke JP, for the STROBE Initiative.	Ann Intern Med. 2007;147:573-7. https://doi.org/10.7326/0003-4819-147-8-200710160-00010
Diagnostic or prognostic accuracy studies	STARD 2015: An Updated List of Essential Items for Reporting Diagnostic Accuracy Studies. Bossuyt PM, Reitsma JB, Bruns DE, Gatsonis CA, Glasziou PP, Irwig L, et al.; for the STARD Group.	BMJ. 2015;351:h5527. https://doi.org/10.1136/bmj.h5527
Economic evaluation	Consolidated Health Economic Evaluation Reporting Standards 2022 (CHEERS 2022) Statement: Updated Reporting Guidance for Health Economic Evaluations. Husereau D, Drummond M, Augustovski F, de Bekker-Grob E, Briggs AH, Carswell C, et al.; CHEERS 2022 ISPOR Good Research Practices Task Force.	BMC Med. 2022;20:23. https://doi.org/10.1186/s12916-021-02204-0
Clinical practice guidelines	The AGREE Reporting Checklist: a tool to improve reporting of clinical practice guidelines. Brouwers MC, Kerkvliet K, Spithoff K, AGREE Next Steps Consortium.	BMJ. 2016;352:i1152. https://doi.org/10.1136/bmj.i1152
Randomized trials	CONSORT 2010 Statement: updated guidelines for reporting parallel group randomised trials. Schulz KF, Altman DG, Moher D, for the CONSORT Group.	Ann Intern Med. 2010;152:726-32. https://doi.org/10.7326/0003-4819-152-11-201006010-00232
Systematic reviews	The PRISMA 2020 statement: An updated guideline for reporting systematic reviews. Page MJ, McKenzie JE, Bossuyt PM, Boutron I, Hoffmann TC, Mulrow CD, et al.	BMJ. 2021;372:n71. https://doi.org/10.1136/bmj.n71
Qualitative studies	Standards for reporting qualitative research: a synthesis of recommendations. O'Brien BC, Harris IB, Beckman TJ, Reed DA, Cook DA.	Acad Med. 2014;89:1245-51. https://doi.org/10.1097/ACM.0000000000000388

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most frequently used by surgeons who conduct research and wish to publish their findings.

Compliance with ethical standards

Informed consent: This study is a literature review, and as such there is no need for informed consent or Institutional Ethics Committee approval.

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Author's contribution:

- Conception and design of the study: Monica Bejarano, Patrizio Petrone.
- Acquisition of data: Monica Bejarano, Patrizio Petrone.
- Data analysis and interpretation: Monica Bejarano, Patrizio Petrone.
- Drafting the manuscript: Monica Bejarano, Patrizio Petrone.
- Critical review and final approval: Monica Bejarano, Patrizio Petrone.

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