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Methodological letter

Observational studies in surgical research☆

El estudio observacional en investigaciones quirúrgicas

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Observational studies continue to play an important role in surgery, because they can help to understand causality over time[1], and they have the following advantages: (a) examining a theoretically unlimited number of outcomes; (b) explore unusual exposures on a large scale; (c) allow nested studies. Randomized clinical trials, although recognised as the best or ''gold standard'' type of research study, have limitations, at least in special situations. Limitations mainly include: (a) they tend not to scale beyond the test population; (b) they usually do not clarify how the results apply to an individual patient; (c) at best, efficacy is the average effect within the trial population[2]. Furthermore, the multiple benefits these studies offer are often at the expense of accuracy, efficiency, and scope[2].

Type of observational studies

The term ''observational'' identifies studies in which patients are not assigned to treatments according to specific criteria, leaving the decision to the doctors or patients.

There are several types of observational studies (Table 1, mod from Ref. 3). The most used and pertinent to surgery are usually cohort studies, case-control, case series and case reports[4].

In cohort studies, researchers define a population affected by a specific condition or a population that has undergone surgical treatment or a diagnostic test, and they follow this population over time, after the treatment or the test.

Depending on the temporal direction of the cohort studies, it is possible to identify prospective and retrospective studies. In prospective studies, after identifying patients, researchers observe the evolution by looking forward in time, that is, they follow the results. For retrospective studies, the data are collected from patients who have already been previously treated, back in time.

Prospective and retrospective studies have advantages and disadvantages. Prospective studies allow data to be collected in ''real time'', they reduce the risk of lost data; however, they require more time to be performed and to analyse the data, tend to be more expensive, and require more time for researchers. Retrospective studies can be performed more quickly and with lower costs; however, it is often difficult to collect missing data, patients are more likely to not complete follow-up, and it may be necessary to review clinical reports, which entails longer times. In addition, researchers can already know the evolution of each patient.

Case-control studies are retrospective and compare a population that has had a known outcome with patients or individuals with similar characteristics who have not had the same treatment outcome. These studies are important for infrequent pathologies. They have the advantage of being able to be completed quickly, of not requiring prolonged prospective follow-up, and of not involving high costs. The main

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Table 1 – More relevant observational studies (mod. from These[3]).

Type of study	Observation	Risk assessment/calculation	Temporal direction
Ecological	Prevalence (estimated)	Prevalence ratio	Retrospective
Cohort study	Prevalence	Odds ratio	Retrospective
		Prevalence odds ratio	Prospective
		Prevalence ratio	
		Prevalence difference	
		Attributable risk	
		Relative risk	
		Risk ratio	
		Hazard ratio	
Case-control	–	Odds ratio	Retrospective
Cross sectional	Prevalence at a given time	Odds ratio	Pro-retrospective
		Prevalence odds ratio	
		Prevalence ratio	
		Prevalence difference	

disadvantage of case-control studies is the possibility of a selection bias in the control population, due to the fact that researchers can choose the patients in that group. Another limitation is the impossibility of calculating the incidence of a condition in the population, having the study group already had a result of interest.

Cross-sectional studies ''take a snapshot'' of a condition in a population at a given point in time. The objective is to assess a larger population of those who have already had such a result. All information is collected at a given moment, regardless of time. The advantage is the ability to calculate the prevalence and incidence of a condition. However, it may happen that several data are not collected or that the data are not reliable, being the assessment punctual in time.

Finally, studies defined as case series or isolated case reports usually present a patient or patients with an infrequent condition or with an unexpected evolution associated with treatments or tests that are usually used in routine clinical practice. Although they are considered of low scientific level, they can be useful to offer perspectives based on the experience of the authors. In this perspective, one should note that the IDEAL Framework (Innovation, Development, Exploration, Assessment, Long-term monitoring), developed to describe how innovations in surgery should be approached to ensure easier translation to surgical care, identified case reports and case series to be the adequate type of studies to fit in the stage of ''Innovation'' and ''Development'', respectively, whereas RCT/prospective studies, RCT, and Database studies are better suited for Exploration, Assessment and Long-term monitoring[4,5].

However, it is important not to use case series and case reports to reach firm scientific conclusions and it is appropriate not to include this typology of studies in systematic reviews or meta-analyses.

Observational studies in surgery: limitations and strengths

The main limitations of observational studies in surgery include patient selection bias, due to the inclusion/exclusion of patients for reasons that do not depend on randomization. In surgery, this can be translated, for example, into the omission/lack of inclusion of a patient who has had a negative evolution after a procedure. Other problems are the accuracy of the information entered, and the amount of data available. These limitations are more accentuated in studies that examine a drug in surgical patients vs placebo or another drug (*Type 1 Study*)[6]: randomized trials will be more suitable for this type of study.

However, observational studies in surgery make it possible to avoid ethical problems of randomization before surgery or assignment to sham surgery; they do not involve high costs; and – being less selective about randomized trials – they allow the inclusion of more patients with less rigid criteria. Specifically in surgery, especially for studies that compare not only the procedure but the overall management of the patient (*Type 2 Study*) or for studies that compare surgery vs no surgery (*Type 3 Study*), observational studies conducted in a methodologically correct way can reach conclusions similar to those of randomized trials[6]. In addition, data from observational studies, including larger populations followed for a longer time, allow to demonstrate effects that cannot be observed in randomized trials.

Lastly, the *creativity* that characterizes surgery – and that has allowed important advances – cannot be captured by randomized trials[6].

Future perspectives

Although there are several limitations in observational studies, in recent years the development of advanced statistical methods (e.g., instrumental variable analysis, Mendelian randomisation, Bayesian networks, process tracing) has improved the quality of observational studies in surgery. Lastly, the possibility of establishing collaborative networks to carry out multicentre studies has been facilitated in recent years, and has shown to be able to produce, in rapid times, relevant data for the daily clinical practice of surgeons, useful to offer safer treatments to patients or to promote patient empowerment, due to the possibility of offering patients broader perspectives of each treatment, moving towards shared decision-making.

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