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RESEARCH AND SURGERY

Error, bias and confusion: It is necessary to keep them in mind to control them

Error, sesgo y confusión: Es necesario tenerlos en mente para controlarlos

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Abstract

Introduction. The validity of knowledge derived from a study depends on the absence of error. All epidemiological designs are susceptible to errors, so researchers must carefully plan each phase of their study to control them.

Methods. Narrative review of the literature, summarizing the salient points related to error, bias and confusion in surgery-related research.

Results. When formulating a research question, two types of errors can occur that lead to wrong conclusions: type 1 error (alpha), in which differences are observed when in reality there are none, and type 2 error (beta), in which no differences are found when in reality there are. The list of possible biases is long and can originate from three sources, some belonging to the subject of the study, others to the researcher, and finally, others that depend on the instrument or system of information collection.

Conclusion. The validity of a study depends on the absence of errors; however, it is not possible to completely eliminate biases from epidemiological studies. In general surgery research, even in the simplest designs such as case reports, errors and biases can occur. Therefore, one of the objectives of a researcher should be to reduce errors to a minimum, identify biases that cannot be avoided, determine their impact, keep them in mind when interpreting the results and express this in the publication of the article.

Keywords: research; research design; scientific experimental error; bias; confusion; general surgery.

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Resumen

Introducción. La validez del conocimiento derivado de un estudio depende de la ausencia de error. Todo diseño epidemiológico es susceptible de errores, por lo que los investigadores deben planear cuidadosamente cada una de las fases de su estudio para controlarlos.

Métodos. Revisión narrativa de la literatura, resumiendo los puntos sobresalientes relacionados con error, sesgo y confusión en investigación relacionada con cirugía.

Resultados. Cuando se formula una pregunta de investigación se puede incurrir en dos tipos de errores que llevan a conclusiones equivocadas: el error tipo 1 (alfa), en el que se observan diferencias cuando en realidad no existen, y el error tipo 2 (beta), en el que no se encuentran diferencias cuando en realidad las hay. La lista de posibles sesgos es larga y pueden estar originados en tres fuentes, unas propias del sujeto de estudio, otras del investigador, y finalmente, unas que dependen del instrumento o sistema de recolección de la información.

Conclusión. La validez de un estudio depende de la ausencia de errores, sin embargo, no es posible eliminar por completo los sesgos de los estudios epidemiológicos. En investigación en cirugía general, incluso en los diseños más sencillos como los reportes de caso, puede haber errores y sesgos. Por eso, uno de los objetivos de un investigador debe ser reducir al mínimo los errores, identificar los sesgos que no se pueden evitar, determinar su impacto, tenerlos en mente en la interpretación de los resultados y manifestarlo en la publicación de su artículo.

Palabras clave: investigación; proyectos de investigación; error científico experimental; sesgo; confusión; cirugía general.

Introduction

The validity of the knowledge derived from a study depends on the absence of error [1]. The result of a study is expected to reflect the true effect of an exposure; however, it should be kept in mind that the findings may have another explanation, in part due to chance error, bias or confounding.

Any epidemiological design is susceptible to errors, so researchers must carefully plan each phase of their study to control them and avoid reaching wrong conclusions.

Definitions

When formulating a research question, two types of errors can be incurred that lead to wrong conclusions: type 1 error (alpha), in which differences are observed when in reality they do not exist, and type 2 error (beta), in which no differences are found when in reality there are. These errors are produced by random error, systematic error (bias), or confusion.

Random or unsystematic error occurs when repeated measurements vary in unpredictable ways. It cannot be avoided, but its impact on the results can be quantified by calculating the p value and confidence intervals [2]. It can be reduced with statistical tools, by correctly estimating the sample size. Thus, the random error decreases with increasing sample size or study population, it is not constant in each measurement, and it does not always occur in the same direction [3].

Systematic error or bias consists of an effect that tends to produce results that systematically deviate from the true value; it is defined as a differential error [1]. The effect of bias will be an estimate, over or under the true value, depending on the direction of the systematic error, which directly affects the internal validity of the study. Its effect is difficult to evaluate, its magnitude is not easy to quantify, and it is not affected by sample size.

Types of biases

The biases can be differential or non-differential, which are those that affect all comparison groups equally, tending to dilute the true existing association. As a consequence, study subjects are assigned to an incorrect outcome category, leading

to incorrect estimation of the association between exposure and outcome. More than 50 types of bias have been identified in epidemiological studies. To simplify your knowledge, they have been grouped into two large categories, selection and information.

Selection biases

Selection bias refers to any error arising from the identification of the study population and appears when there is a systematic difference between those who participate in the study and those who do not (affecting generalizability) or between those in the treatment group of a study and those in the control group (affecting comparability between groups).

Up to 35 different types of selection bias have been described, whose common element is that the relationship between exposure and disease differs in the subjects who participate in the study compared to those subjects who, being eligible, are not included in the study.

Prevalence or incidence bias (Neyman bias)

This type of bias occurs when a disease that causes premature death is evaluated and, as a consequence, deceased individuals cannot be included in the group of cases at the beginning of the study. When the permanence of participants in the study is determined by an event, which is of different magnitude for the exposed and non-exposed groups, there will be the possibility that the results will be distorted. For this reason, it is recommended to maximize retention and follow-up rates.

Admission bias (bias, fallacy, or Berkson's paradox)

Bias occurs when cases and controls are recruited among hospitalized patients, since this group is not representative of the population that has the disease. This bias can be avoided by selecting controls among people admitted to the hospital in the same period of time, but for other causes (in different services), to ensure a wide variety of diseases, and excluding diagnoses positively or negatively related to the risk factor under study; The diseases included as controls must have a probability of hospital admission similar to that of the cases. An alternative to solve the problem posed by this type of bias is the use of two control groups.

Sampling bias

Sampling bias describes the scenario in which some individuals within a target population are more likely to be selected for inclusion than others. It occurs when groups of individuals are over- or under-represented during the data collection process.

Allocation bias

Allocation bias is introduced into a study when researchers do not properly randomly assign participants to different groups (exposed and unexposed or cases and controls, for example), causing a systematic difference between participants in the study groups (in addition to the intervention being studied).

Loss to follow-up or attrition bias

Loss of participants to follow-up is a particular problem associated with cohort studies. Attrition bias refers to the systematic differences that exist between participants who remain in a program and those who drop out. Bias may be introduced if individuals lost to follow-up differ from those remaining in the study with respect to exposure and outcome. The differential loss of participants from groups in a randomized controlled trial is known as attrition bias.

Non-response bias

Non-response in a survey is defined as the impossibility of obtaining the participation of all the selected sampling units. Nonresponse bias leads to a distortion of results due to differences between respondents who answer specific questions and those who fail to answer the questions [4].

The population estimates obtained from the sample of subjects who respond to the questionnaire may differ from the estimates that would have been obtained if the total sample had responded to the questionnaire. This difference occurs when the subjects who do not respond

systematically differ from those who do respond, in reference to those characteristics that are of interest in the study. It is considered that if there is a non-response percentage of 20% the study is biased [2].

Their impact can be mitigated by corrective strategies, such as sample substitution, in which non-responders are replaced by individuals randomly selected from the study sample or by individuals with similar characteristics to the non-responders (matched replacements). Another option is intention-to-treat analysis, one of the cornerstones in the analytical strategy of clinical trials, which allows preserving the benefits of random assignment [3].

Information biases

Information bias is introduced by the method used to collect the information. It occurs due to the systematic differences that exist in obtaining data in the evaluated groups; if the collection of information is different between groups, it causes the conclusion of the association to be wrong.

There are three sources of information bias, some specific to the subject of the study, observed or responding, others from the researcher, interviewer or surveyor, and finally, some that depend on the instrument or information collection system [5].

Recall or memory bias

In retrospective studies, the quality of some data depends on the ability of subjects to accurately remember previous events. When information provided by patients regarding exposure differs between cases and controls, recall bias may occur. Generally, memory is of better clarity or precision, or there is a greater effort to remember, among those who develop the disease, leading to an overrepresentation of exposed subjects among the sick.

To control it, the ideal would be to do a prospective cohort study, but this is not always possible for reasons of cost and time, therefore, the option remains to correctly measure or collect the information provided by both groups, using an objective and validated tool to ensure that the subjects remember more accurately. You can also try to find the same information about exposure from two different sources, for example, the index subject and his or her spouse, without forgetting the implications of proxy informants.

Participant bias

Contrary to the previous situation, this bias occurs when subjects "decide" or classify themselves in a certain state derived from knowing their exposure. It happens when non-objective information is collected, such as the perception of pain. To prevent this, it is necessary to seek, whenever possible, to verify the information reported by research subjects.

In general terms, it is recommended to use objective measures, such as measurement scales that have already been validated in other studies, to improve the precision of our evaluation and to subsequently compare the results obtained with other similar studies. From the design of the study and the information collection strategies, the measurement scales and thresholds that are supported in the literature must be defined, before beginning to capture the data, to avoid biasing the results.

Social desirability bias

It refers to the tendency of study participants to answer questions in a way that makes them or their actions appear more appropriate or desirable to the evaluator.

Attention bias (Hawthorne effect)

This bias is caused by the modification in the behavior of the study subjects when they know they are being observed [6]. For example, if an evaluator participates in a particular session to discuss how an intervention is being carried out, facilitators and participants may alter their behavior to "impress" the evaluator, without even realizing they are doing so [4].

Observer bias

The observer's prior knowledge of the hypothesis, exposure, or disease state can lead to observer bias. That information can affect how the researcher collects, measures, or interprets the data in each study group. There is, voluntarily or not, a collection of information closest to the verification of the research hypothesis. The researchers (who know the study hypothesis) decide to classify the participants into some exposure group derived from their prior knowledge and not from the information that the research protocol indicates.

Interviewer bias

Interviewer bias occurs when an interviewer, consciously or unconsciously, asks leading questions to obtain information that would not be asked if they did not know the disease state. The interviewer forces the answers of the participants, omitting pre-established questions, adding new ones or skipping the stipulated protocol for the interviews, which can ultimately systematically influence the answers given by the interviewees [5].

There are several strategies that can be implemented to prevent these two types of bias. Among them, it is essential to provide good training for interviewers so that they obtain data in a standardized manner and prevent them from knowing (or blinding) the study hypothesis, the diagnosis (or outcome) of the study subjects and the exposure status of the participants [1]. Well-standardized data collection protocols should be developed.

Another is the initial evaluation of the concordance or agreement between the evaluators' measurements, for which appropriate prior training in the correct use of the instruments and determinations is also required.

Surveillance bias

When a target population is monitored more closely, the probability of identifying the disease in subclinical phases increases [5]. As a consequence, the presence of the disease is recognized in advance in those exposed to a greater extent than in those not exposed, therefore, the number of patients in initial stages may be greater among those exposed.

To prevent this bias, blinding is recommended, including more than one evaluator to determine the presence of the disease, who preferably are unaware of the exposure of the participants. Another option is stratification by disease severity at diagnosis.

Procedural bias (Feinstein bias)

It occurs when the group that presents the dependent variable turns out to be "more interesting" to the researcher than the control group, so during the measurement there is greater concern or interest in obtaining information from the first group, which ends up benefiting from greater thoroughness in observation [6].

Detection bias

Detection bias occurs when the way results are collected or verified is different between groups. It occurs when diagnostic tools other than those defined in the study protocol are used, which can lead to reclassification, changes in staging or prognosis.

Adaptation bias

It occurs when study subjects initially assigned to a group in an experimental study decide to migrate to another group because they prefer the other intervention or treatment option. This is avoided by the randomization process and double blinding in controlled clinical trials.

Measurement error

Errors in measuring exposure or outcome (disease) are an important source of bias in epidemiological studies. Therefore, when conducting studies, it is important to evaluate the quality of the measurements, determining validity and precision.

When a "gold standard" is available, it must be compared against the tool with which the measurements will be made to determine its reliability. However, in clinical practice it is very common that there is no safe reference standard in accordance with what is established according to evidence-based medicine [7] and the measurements must be validated indirectly and incompletely, comparing

them with the best conventional clinical evaluation available in the environment.

One strategy is repetition of measurements. Repeatability can be checked with the same observer making several measurements at different times or with different observers making the measurement on the same subject or sample. To interpret the results, it is useful to divide the variability as follows:

- Intraobserver variation
- Interobserver variation
- Random variation of subjects
- Biased (systematic) variation of subjects

Misclassification

Misclassification refers to the assignment of an individual, an attribute, or a value to a category other than the one to which it is actually assigned.

Differential (non-random) misclassification error occurs when the proportion of subjects who are misclassified differs between study groups. That is, the probability of the exposure being misclassified depends on the disease state, or the probability of the disease state being misclassified depends on the exposure state. This leads to an underestimation or overestimation of the true association, causing a more serious problem.

On the contrary, the non-differential (random) classification error increases the similarities between the groups under study, thereby underestimating (decreasing or diluting) the real strength of association between exposure and disease.

The use of substitute informants (proxies), whether due to some incapacity of the study subjects or because they have already died, can also give rise to differential exposure classification bias [1]. Depending on the relationship between the surrogate informant and the individual included in the study, their responses about the exposure of interest may range from exaggeration to denial.

Publication bias

Publication bias is caused by the refusal of surgical journals to publish negative results [8]. In research projects, it is common for studies with negative results to be excluded and unpublished data to be ignored, especially studies published in non-indexed journals.

Confusion

Confounding occurs when an association is distorted because there is "another risk factor" (or a third variable) that correlates with the exposure and at the same time with the outcome, but independently of the exposure investigated. That variable is also independently associated with the outcome (i.e., it is a risk factor) but is not in the causal pathway between exposure and disease.

Then, there is an unequal or unbalanced distribution in the comparison groups of a third variable, which is called the confounding variable, and leads to a distortion of the study estimates. Because distribution is unequal, the true relationship between the exposure and the evaluated effect or outcome is altered.

Confusion control

To identify a confounding or confounding variable, the raw value of the effect (by estimating the relative risk or odds ratio of the variable under study) can be compared with the adjusted value (obtained through stratification applying logistic regression models). If a difference of 10-15% is obtained, it is considered that there is confusion [6].

In a significant number of studies, age and sex are confounding variables. Other potentially confounding variables include socioeconomic status, race, and place of residence.

There are two ways to control confusion: from the design, through randomization for sample selection or matching, to stratified analysis (by the probable variable that causes confusion) or multivariable analysis.

Effects of confusion

When the presence of a confounding variable is not involved, the results can be affected in four ways [4]:

- Spurious association, which is an apparent association even though no real association exists.

- Hidden association, where there is apparently no association even though a real association exists.
- Positive confounding factor, which enhances (or overestimates) a true association.
- Negative confounding factor, which masks (or underestimates) a true association.

Final considerations

The researcher can try to prevent errors and biases in the study design phase through random assignment in clinical trials, restriction according to the possible confounding variable, or matching, used mainly in case-control studies.

Once the information has been collected, an attempt can be made to control biases in the analysis phase, using stratification, to analyze subgroups separated by covariates or strata, standardization, to compare according to the identified confounding variables, or multivariate statistical analysis, to simultaneously evaluate several variables and determine the existence of possible confounding variables, estimating the effect of exposure.

Conclusion

The validity of a study depends on the absence of errors; however, it is not possible to completely eliminate biases from epidemiological studies. Selection bias is introduced when the subjects studied are not representative of the target population about which conclusions are to be drawn, while information bias arises from errors in the measurement of exposure or disease.

In general surgery research, even in the simplest designs such as case reports, there may be errors and biases. Therefore, one of the objectives of a researcher should be to minimize errors, identify biases that cannot be avoided, determine their impact, keep them in mind when interpreting the results and express them in the publication of their article.

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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- 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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