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STROBE initiative: guidelines on reporting observational studies

ABSTRACT

Reporting of observational studies is often inadequate, hampering the assessment of their strengths and weaknesses and, consequently, the generalization of study results. The initiative named Strengthening the Reporting of Observational Studies in Epidemiology (STROBE) developed a checklist of 22 items, the STROBE Statement, with recommendations about what should be included in a more accurate and complete description of observational studies. Between June and December 2008, a group of Brazilian researchers was dedicated to the translation and adaptation of the STROBE Statement into Portuguese. The present study aimed to show the translation into Portuguese, introduce the discussion on the context of use, the potential and limitations of the STROBE initiative.

DESCRIPTORS: Observational Studies. Epidemiologic Studies. Statistical Methods and Procedures. Health Research Evaluation. Checklist. Translations.

Clinical trials and observational studies in the context of modern biomedical research

Randomized clinical trials have been described as the gold standard for biomedical research as they show high internal validity and, consequently, greater accuracy in the efficacy and effectiveness evaluation of several therapeutic and preventive health practices.⁴

However, public health studies have frequently dealt with problems where this study design is not adequate and/or ethical, or, yet, for which the translation of randomized controlled trial findings into concrete intervention and/or treatment conditions faces great difficulties due to the lack of external validity of findings obtained in a clinical trial context. According to Victora et al,²⁶ randomized clinical trials frequently represent an inadequate choice to assess the performance and impact of large scale interventions, especially in contexts of heterogeneity, whether they are social, economic and/or geographic in nature. In addition, there are operational aspects that can hinder or even preclude the implementation of clinical trials: individuals may not want to be randomized for a given intervention group, randomized selection may not be possible or ethically acceptable in the research context, or, yet, only participants with certain characteristics might accept to be selected.³¹ In view of the impossibility or inadequacy of implementation of randomized clinical trials, whether due to ethical or operational questions, observational studies appear as a more feasible solution and, in cohort studies, are relevant alternatives to evaluate the impact of interventions throughout time.²²

Observational studies are more adequate to evaluate rare or late side effects associated with certain treatments and they often provide a more accurate indication of what can be achieved in routine clinical practice, once they take

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advantage of a given situation and observe its results, which can be context-dependent.¹⁷ A clear example that clinical trials are unable to find rare and/or late side effects is the need to develop Phase IV (post-commercialization) clinical trials of new drugs and/or new therapies. The recent recall of drugs approved in all pre-clinical and clinical stages of research, approved by regulatory organizations such as the Food and Drug Administration (FDA) in the United States, clearly documents clinical trial limitations and the necessity of a continuous pharmacovigilance.¹²

The adverse effects of non-steroidal anti-inflammatory drugs on cardiovascular morbidity-mortality has been documented in studies with large sample sizes and long-term follow-up. Until then, these side effects had been imperceptible in the context of clinical trials and even of pharmacovigilance, involving a small number of cases and/or having a relatively short follow-up period.¹⁰

Previous data emphasize the importance of observational studies. Quite frequently, randomized clinical trials cannot be conducted due to ethical, political or infrastructure aspects, such as in studies that evaluate interventions effectiveness that have favorable empirical evidence on their behalf, even if only based on observational studies, especially evident for vulnerable populations. This is the case of harm reduction programs targeting injecting drug users, a public health approach that had never been evaluated using randomized clinical trials, based on empirically based evidences exclusively derived from observational studies where this intervention may prevent new infections by different blood-borne and/or sexual transmitted pathogens.

A second limitation to the performance of this type of studies includes their associated costs and the time necessary to obtain meaningful results. Observational studies are less expensive and enable data analysis in a shorter period of time, a vital aspect towards timely public policy design, particularly in low- and middle-income countries and in emergency situations, As an example, a study aimed at evaluating the association between cholesterol levels in the diet and subsequent coronary disease could be considered.

A third issue refers to the fact that observational study samples are frequently more representative of the intervention target population than randomized clinical trials, which tend to be performed in specific environments, such as referral hospitals, dealing with patients who can adhere to very restrictive treatment and follow-up protocols. Finally, many studies that are idealized to be randomized clinical trials become, in practice, very close to observational studies, when protocols are not followed, when patients are lost to

follow-up, and when there are missing data, among other problems.

Presentation of observational study results in biomedical research

The description and presentation of study findings must be organized in a clear way, since the study reliability depends on a critical evaluation, made by editors, the scientific community and readers, about the study strengths and weaknesses associated with its design, performance and analysis. A clear and coherent description is also necessary to enable judgment of whether and how study results should be incorporated into major interventions and/or public policies.^{26,27}

However, many epidemiological studies (observational and experimental) published in scientific journals do not show essential information, described in a clear and adequate way.^{23,28-30,32}

A systematic review performed in 2008 tried to evaluate the quality of confounding reporting in observational studies,¹¹ identifying that a small number of published studies adequately describe the role of potential confounding variables in their results.

Trying to identify the lack of clarity in epidemiological study description, a group of European and American researchers developed a strategy aiming to show items that should be described in the report of randomized clinical trials – the Consolidated Standards of Reporting Trials (CONSORT) strategy.³ The CONSORT comprises a checklist of 22 items, which should be described when such studies are reported. This initiative has already been adopted by more than 300 scientific journals and its use has been associated with a better report of those studies and has been regularly reviewed since its first publication in 1996.^{2,6}

In the last 15 years, a dozen checklists have been developed, aiming to improve the reporting quality of several study designs. In addition to the CONSORT, the Quality of Reporting of Meta-Analyses (QUORUM) initiative,¹⁵ the Meta-Analysis of Observational Studies in Epidemiology (MOOSE)²¹ and the Standards for Reporting of Diagnostic Accuracy (STARD) are available in the specialized literature.³

Following this trend, a group of researchers developed the Strengthening the Reporting of Observational Studies in Epidemiology (STROBE) initiative, which includes recommendations to improve the quality of observational study reporting.³⁰

The STROBE Initiative

The items comprising STROBE are associated with information that should be present in the title, abstract,

³ CONSORT Statement 2010. [cited 2010 Apr 12] Available from: <http://www.consort-statement.org/consort-statement/>

background, methodology, results and discussion of scientific papers describing observational studies. A total of 18 items are common to cohort, case-control and cross-sectional studies and four items are specific for each one of the three study designs. The STROBE Initiative provides a model that can be followed by authors of observational studies and aims to contribute towards a more adequate report of these studies and, consequently, facilitating a critical reading of these publications by editors, reviewers and readers in general.³⁰

The STROBE Initiative was originally published in English. Subsequently, independent research groups from several countries translated the observation checklist and the basic principles of this initiative into other languages, aiming to promote the principles that should guide the report of observational studies to an ever wider public.^{1,8,9,16,20,28,29}

The present study shows the first Portuguese version of the STROBE Initiative basic principles, which was developed in partnership between researchers from the *Fundação Oswaldo Cruz* (Oswaldo Cruz Foundation) at the *Universidade Federal do Rio de Janeiro* (Rio de Janeiro Federal University) and the researchers who developed this initiative.

Objective and Use of the STROBE Initiative

The checklist and documents describing the STROBE Initiative were developed in a collaborative process that included researchers working with epidemiology, statistics and research methodology, in addition to the editors of several scientific journals. The purpose of the STROBE Initiative is to provide recommendations on how to report observational studies in a more adequate way. One must remember, however, that these recommendations are not prescriptions for designing or conducting studies. In addition, although clarity in description is a prerequisite for the assessment, the checklist should not be used as an instrument to assess observational study quality.³⁰

The international literature comprises articles where the reasons to include different checklist items, the methodology used and the examples considered as adequate descriptions of items involved in this checklist are explained in detail.^{24,25} The STROBE Initiative recommends the use of the checklist combined with explanatory articles on its different items.^b

Translation of the STROBE Initiative into Portuguese

In 2008, one of the authors of the present study (MM), together with the researcher responsible for

the international STROBE Initiative (Mathias Egger), established a partnership to translate this document into Portuguese. The team responsible for the STROBE Initiative authorized the Brazilian group to develop a Portuguese version of the checklist on which the STROBE Initiative is based.

The initial translation was independently performed by two authors of the present article (MM & LC). After reaching a consensus on the final translation, this text was sent to the researchers who had not been involved in the translation process (FIB, MMFM, CMFPS), who reviewed it. Finally, all authors met to obtain a final version of the text, aiming to develop a checklist comprising the most commonly used terms in studies and publications in the epidemiology of observational studies.^c The items included in the checklist are widely discussed by the authors of the STROBE Initiative (webannex).^c

Recent developments of the STROBE Initiative: strengths and weaknesses

The STROBE Initiative has raised a growing debate in the scientific literature. According to some authors, the initiative has been viewed as an important strategy which, in the near future, may be associated with the improvement in the report of observational studies.^{5,11,20} However, other authors see the Initiative with reservation. Editors are reticent, since the STROBE Initiative seeks to formalize the description of studies performed in a research field as heterogeneous as epidemiology, particularly when dealing with observational studies. According to them, such initiative could jeopardize the performance and description of unique and creative studies.⁷ Some researchers believe that the STROBE Initiative is important for this field of knowledge, but it must be seen as an initiative under permanent review, since this kind of strategy represents a consensus of a specific group, in a given moment.¹⁸⁻²⁰

According to MacMahon & Weiss,¹⁴ these checklists can be useful for a researcher in the beginning of his/her career, for whom this type of organization can facilitate the report of a study carried out by them. However, these authors state that the principles on which these checklists are based should be observed in the beginning of the process, at the very inception of the study, then comprising the design, conduction and analysis of observational studies, and not exclusively at the moment when the research is reported. In addition, authors highlight the risk that, for situations where the author only becomes aware of these checklists when writing their article, they would report what they should have done, and not what they actually did.

^b STROBE Statement. Strengthening the reporting of observational studies in epidemiology. Strobe checklists: version 4. Berna: University of Bern; 2007 [cited 2010 Apr 12]. Available from: <http://www.strobe-statement.org/index.php?id=available-checklists>

^c The Portuguese versions of the checklist and the article by von Elm et al (translated by Malta M, Cardoso LO) are available as supplemental material to this article on the internet at: www.scielo.br/rsp

Apart from criticisms, the STROBE Initiative can be used as another instrument to guide the development of observational epidemiological studies, in addition to the possibility of being used as a bibliography for undergraduate and postgraduate students, aiming to contribute to the qualification of new generations of researchers.

Authors in this study recognize that the STROBE Initiative must be seen as an ongoing process, open to reviews, recommendations, criticisms and new evidence. At the moment, this initiative is limited to the three main designs of observational studies and is in its

first version. According to the authors of the STROBE Initiative, initiatives seeking to adapt the checklist to other designs are welcome, such as case-crossover studies or ecological studies, in addition to topics associated with specific areas. The first extension of STROBE is currently being developed for studies that evaluate the association between diseases and genes. It has been called the "Extension to Genetic Association Studies (STREGA) Initiative".¹³ Researchers who have an interest in developing extensions of the STROBE Initiative can contact the coordination group through the initiative's website, aiming to avoid the duplication of efforts.

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