

Critical Appraisal of Reporting Quality of Case-Control Articles Indexed in SID Website Based on STROBE Statement

Maryam Hadavi¹, Mohsen Rezaeian², Razieh Zeinali³

¹ Department of Anesthesiology, Molecular Medicine Research Center, Research Institute of Basic Medical Sciences, Rafsanjan University of Medical Sciences, Rafsanjan, Iran

² Department of Epidemiology and Biostatistics, Occupational Environmental Research Center, Rafsanjan University of Medical Sciences, Rafsanjan, Iran

³ Department of Medicine, School of Medicine, Mashhad University of Medical Sciences, Mashhad, Iran

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Abstract- The STROBE (strengthening the reporting of observational studies in epidemiology) statement presents recommendations to improve the reporting of observational studies. This study aimed to evaluate the quality of reporting the case-control articles indexed in the Scientific Information Database (SID). This descriptive study was conducted in 2016 in the all case-control articles indexed in the SID website over a 10-year period (2006 to 2015). The researchers visited the SID website and used the keywords of "case" and "control" in titles or keywords of the articles. Then, the STROBE checklist was completed for each article. Data were analyzed using descriptive statistics. The first item of the checklist was observed in 100% of the studied articles. None of these articles had described "duration of exposure" and "how missing data were addressed." None of these articles had used the flowchart. The quality of reporting in studied articles was acceptable, but some of the items in the STROBE checklist need more attention.

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Introduction

Health care requires sufficient knowledge of the causes of disease, diagnostic approaches, prognosis and treatment of diseases. Randomized trials provide valuable evidence about the interventions and treatments of disease. However, observational studies play an important role for answering many questions in medical research (1), so that almost 9 of 10 published articles in medical journals are devoted to observational studies. Most of the studies investigating the causes of disease are conducted as a cohort, case-control, and cross-sectional formats. Although the observational studies would be extremely rewarding, they might not be well reported (2), and thus the results of these studies are not traveled correctly and completely to readers.

The researches should be reported transparently, so that the readers should clearly understand the aim of the researchers, the study design, how to implement, and achieved results. The validity of a study depends on the reader's critical appraisal on the strengths and weaknesses

of the study design, implementation, and analysis of the results (3). In October 2007, outstanding researchers from the Netherlands, Switzerland, Germany, England, Denmark and the U.S.A presented a checklist for the evaluation of results obtained from observational studies, which was greatly noted. This checklist contains points that should be mentioned in the reporting of observational studies, which is also known as STROBE Statement (Strengthening the Reporting of Observational Studies in Epidemiology). The purpose of this checklist is to present recommendations to clarify the design, methods, and findings of observational studies and is a tool to improve the reporting of observational studies. Within the STROBE Statement, three main types of observational studies including cohort, case-control and cross-sectional ones have been taken into consideration (4).

In a study titled "Case series and descriptive cohort studies in neurosurgery: the confusion and solution," 64 published articles labeled as Case series studies were studied. According to the definition of study types and the use of STROBE guidelines, it was found that only 18

Corresponding Author: M. Hadavi

Department of Anesthesiology, Molecular Medicine Research Center, Research Institute of Basic Medical Sciences, Rafsanjan University of Medical Sciences, Rafsanjan, Iran

Tel: +98 34 34258397, Fax: +98 34 34258497, E-mail address: hadavimaryam@yahoo.com

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articles (28.13%) were true case series, while 46 (71.87%) were mislabeled (5). In addition, the evaluation of the conducted researches in the field of stroke revealed that inclusion criteria were not described in 17 (35%) out of 49 articles published in this field (6).

Insufficient reporting on details reduce the confidence in the results, makes it more difficult to repeat the study and declines the accuracy of available information for conducting important review studies such as a meta-analysis (7). The aim of the present study was to evaluate the quality of reporting in case-control articles indexed in the Scientific Information Database (SID) based on the STROBE Statement, as well as determine the level of compliance with the points mentioned in STROBE checklist in these articles. We hope that recognizing the strengths and weaknesses of reporting on the results of case-control studies could assist the researchers and authors of the studies to identify and manage the problems in preparing these types of articles, improve the quality, and the chances of acceptance of articles for publication in prestigious journals.

Materials and Methods

This descriptive study was conducted in 2016 with the approval of Research Council of Rafsanjan University of Medical Sciences in Iran on the all case-control articles indexed in SID website over a 10-year period (2006 to 2015). Data collection tool was the STROBE checklist that is published in several prestigious journals such as PLOS Medicine and the Lancet (8) with an address of <https://www.strobe-statement.org>. The respective checklist has 22 general items (guidelines) that should be considered in reporting the results of observational studies. In this checklist, there is a guideline on how to write title and abstract and two recommendations on how to write the introduction. Each of the sections of materials and methods, results and discussion has respectively 9, 5 and 4 guidelines. Finally, a guideline entitled "other information" presents the funding source of research. Each of these guidelines has been divided into smaller parts in order to conduct the articles more accurately. In this study, all articles were evaluated in terms of compliance or non-compliance with all major and minor suggestions mentioned in this checklist (overall 51 guidelines).

The researchers visited the Scientific Information Database (SID) website, which is a comprehensive and up-to-date scientific database in the country including various and numerous databases and the only database providing free and unlimited access to scientific resources

and full-text articles, and then used the keywords of "case" and "control" in titles or keywords of the articles to select all case-control studies indexed in the respective database. We completed STROBE checklist for each of these articles in this research, as well as determine the compliance of every studied article with each of the proposals using "Yes" and "No" options on the checklist. In cases where the full text of the article was unavailable in the SID website, necessary information was obtained by referring to the reference libraries. Information obtained from the checklist was encoded, inserted into SPSS software and analyzed using descriptive statistics (frequency, percentage, mean), tables, and charts.

Results

Investigation of SID website demonstrated 120 articles indexed in this site within 10-year period, which have used the terms of "case" and "control" in their keyword or the title, including 79 (65.8%) published in quarterly journals, 23 (19.2%) published in monthly journal, 9 (7.5%) published in weekly journal and 9 (7.5%) published in the bimonthly Journal. The distribution of these articles based on the year of publication is given in figure 1.

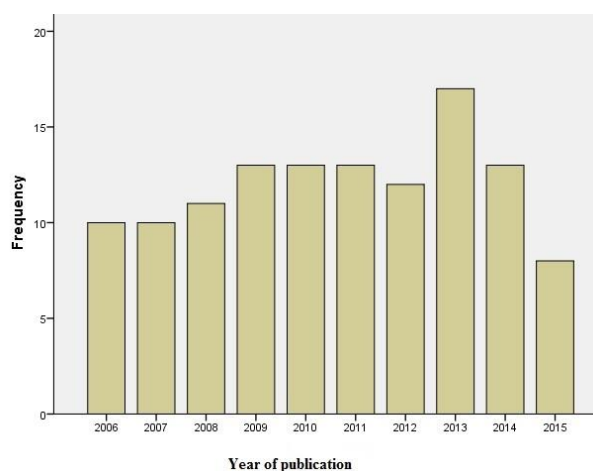


Figure 1. The distribution of case-control articles indexed in the SID website from 2006 to 2015 based on the year of publication

Among the 52 journals publishing the case-control articles in the study period, there were 37 (71.15%) quarterly journals, 7 (13.46%) bimonthly journals, 6 (11.54%) monthly journals and 2 (3.85%) weekly journals. The monthly journal of Tehran University of Medical Sciences with 16 (13.3%) articles and the quarterly Iranian Journal of Epidemiology with 8 (6.7 %) articles had the highest frequency of case-control articles

published in our studied period. Each of the weekly Journal of Isfahan Medical School and quarterly Iranian Journal of Nutrition Sciences and Food Technology were next in rank with publishing 6 (5.0%) articles.

The mean number of authors of these articles was 4.75 ± 1.83 (minimum 1 and maximum 11 authors); the articles with 4 authors (29 articles, 24.2%) had the most frequency.

The results revealed that the first item of STROBE checklist on how to write the title and abstract, i.e., "Indicate the study's design with a commonly used term in the title or the abstract", was observed in all articles and 100% of the studied articles had pointed out the study type. Concerning the writing of different sections in abstract, 78 (65.0%) articles had the balance, and 69 (57.5%) articles had complete compliance with the item

of "what was done and what was found." The full text of 4 articles out of 120 articles was unavailable, so the Introduction, Methods, Results, Discussion, and Source of funding were investigated in 116 articles.

According to the STROBE checklist, the authors of case-control articles should provide a scientific background on the subject, the necessity of conducting a study and the specific objectives in the introduction section; these points were observed in respectively 115 (95.8%), 98 (81.7%) and 109 (90.8%) reviewed articles.

Totally, 26 out of 51 major and minor suggestions listed in the STROBE checklist are devoted to how to write the section of materials and methods. The compliance or non-compliance with these points is shown in table 1.

Table 1. Level of compliance with STROBE checklist recommendations on how to write methods in case-control studies indexed in the SID website from 2006 to 2015 (n=116)

| Items | Yes Number(percent) | No Number(percent) |
|--|------------------------|-----------------------|
| 1 Present key elements of study design early in the paper | 105 (90/5) | 11 (9.5) |
| 2 Describe the locations | 105 (90/5) | 11 (9.5) |
| 3 Describe the periods of recruitment | 51 (44.0) | 65 (56.0) |
| 4 Describe the periods of exposure | 0 (0) | 116 (100) |
| 5 Describe the periods of follow-up and data collection | 8 (6.9) | 108 (93.1) |
| 6 Give the eligibility criteria | 82 (70.7) | 34 (29.3) |
| 7 Give the methods of case ascertainment | 59 (50.9) | 57 (49.1) |
| 8 Give the methods of control selection | 51 (44.0) | 65 (56.0) |
| 9 Give the sources of case ascertainment and control selection | 105 (90/5) | 11 (9.5) |
| 10 Give the rationale for the choice of cases and controls | 42 (36.2) | 74 (63.8) |
| 11 For matched studies, give matching criteria | 76 (65.5) | 40 (34.5) |
| 12 Give the number of controls per case | 82 (70.7) | 34 (29.3) |
| 13 Clearly define all outcomes, exposures | 4 (3.4) | 112 (96.6) |
| 14 Clearly define all predictors, potential confounders, and effect modifiers. Give diagnostic criteria, if applicable | 14 (12.1) | 102 (87.9) |
| 15 For each variable of interest, give sources of data | 103 (88.8) | 13 (11.2) |
| 16 For each variable of interest, give details of methods of assessment (measurement). | 55 (47.4) | 61 (52.6) |
| 17 Describe comparability of assessment methods if there is more than one group | 33 (28.4) | 82 (71.6) |
| 18 Describe any efforts to address potential sources of bias | 11 (9.5) | 105 (90.5) |
| 19 Explain how the study size was arrived at | 33 (28.4) | 82 (71.6) |
| 20 Explain how quantitative variables were handled in the analyses | 45 (38.8) | 71 (61.2) |
| 21 If applicable, describe which groupings were chosen in the analyses and why | 13 (11.2) | 103 (88.8) |
| 22 Describe all statistical methods, including those used to control for confounding | 43 (37.1) | 73 (62.8) |
| 23 Describe any methods used to examine subgroups and interactions | 35 (30.2) | 81 (69.8) |
| 24 Explain how missing data were addressed | 0 (0) | 116 (100) |
| 25 If applicable, explain how matching of cases and controls was addressed | 2 (1.7) | 114 (98.3) |
| 26 Describe any sensitivity analyses | 12 (10.3) | 104 (89.7) |

As shown in Table 1, none of the case-control studies

indexed in SID website from 2006 to 2015 had described

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"duration of exposure" and "how missing data were addressed." In the STROBE checklist, 12 guidelines have been presented to the authors of case-control studies in

order to improve the quality of reporting on the results of the study. Level of compliance with these guidelines in studied articles has been presented in table 2.

Table 2. Level of compliance with STROBE checklist recommendations on how to write results in case-control studies indexed in the SID website from 2006 to 2015

| Items | Yes Number(percent) | No Number(percent) |
|---|------------------------|-----------------------|
| 1 Report numbers of individuals at each stage of the study | 7 (6.0) | 109 (94) |
| 2 Give reasons for non-participation at each stage | 9 (7.8) | 107 (92.2) |
| 3 Consider use of a flow diagram | 0 (0) | 116 (100) |
| 4 Give characteristics of study participants (eg demographic, clinical, social) | 88 (75.9) | 28 (24.1) |
| 5 Give information on exposures and potential confounders | 15 (12.9) | 101 (87.1) |
| 6 Indicate the number of participants with missing data for each variable of interest | 1 (0.9) | 115 (99.1) |
| 7 Report numbers in each exposure category, or summary measures of exposure | 1 (0.9) | 115 (99.1) |
| 8 Give unadjusted estimates and, if applicable, confounder-adjusted estimates and their precision (e.g., 95% confidence interval) | 64 (55.2) | 52 (44.8) |
| 9 Make clear which confounders were adjusted for and why they were included | 24 (20.7) | 92 (79.3) |
| 10 Report category boundaries when continuous variables were categorized | 37 (31.9) | 79 (68.1) |
| 11 consider translating estimates of relative risk into absolute risk for a meaningful time period | 68 (58.6) | 48 (41.4) |
| 12 Report other analyses done—e.g. analyses of subgroups and interactions and sensitivity analyses | 14 (12.1) | 102 (87.9) |

According to table 2, it is determined that demographic, clinical and social characteristics of the participants had been mentioned in most studies (75.9%), but "number of participants with missing data for each variable of interest", and "numbers of outcome events or summary measures over time" only had been reported in

1 article (0.9%). In addition, none of these studied articles had used the flowchart. The STROBE statement guides the authors on how to write the discussion section in case-control articles by five proposals, which its compliance in studied articles are given in table 3.

Table 3. Level of compliance with STROBE checklist recommendations on how to write the discussion section of the study in case-control articles indexed in the SID website from 2006 to 2015

| Items | Yes Number(percent) | No Number(percent) |
|--|------------------------|-----------------------|
| 1 Reference to study objectives | 29 (25) | 87 (75) |
| 2 Summarize key results with reference to study objectives | 108 (93.1) | 8 (6.9) |
| 3 Discuss limitations of the study, taking into account sources of potential bias or imprecision | 56 (48.3) | 60 (51.7) |
| 4 Discuss both the direction and magnitude of any potential bias | 29 (25) | 87 (75) |
| 5 Give a cautious overall interpretation of results considering objectives, limitations, a multiplicity of analyses, results from similar studies, and other relevant evidence | 60 (51.7) | 56 (48.3) |
| 6 Discuss the generalisability (external validity) of the study results | 39 (33.6) | 77 (66.4) |

The source of funding and the role of funders as the last proposal of this checklist had been mentioned in 61 (52.6%) out of the studied articles.

Discussion

The present study aimed to determine the quality of reporting in case-control articles indexed in the SID website over a 10-year period (2006 to 2015) based on the STROBE Statement. The results demonstrated that 65.8% of reviewed articles (79 articles) were published in quarterly journals; this could be due to a higher frequency of quarterly publications compared to the others such as monthly or weekly ones because the 71.15% (37 articles) of case-control articles were published in the quarterly journals during the review period.

Investigating the year of publication of case-control articles indexed in the SID website indicated that the highest and the lowest frequencies belong to the years 2013 and 2015, respectively. As shown in figure 1, the number of case-control articles has been raised from 2006 to 2013. Reduction in the number of these articles in 2015 was probably associated with a delay in publication of some journals.

In the present study, the mean number of authors of case-control articles indexed in the SID website over the studied 10-year period was 4.75 ± 1.83 , and the articles with 4 authors had the highest frequency. In a study of Heidari and Safavi conducted to determine the co-authorship coefficient in articles of Journal of Medical Research, the mean number of authors had been increased from 3.62 ± 1.9 in 2007 up to 4.44 ± 1.9 in 2011 (9). In the article of Marefat *et al.*, titled "A Survey on Collaboration Status of Authors in Producing Scientific Papers in Journal of Clinical Psychology During 2009-2012", the mean number of authors was 3.35 (the standard deviation was not calculated) (10). Also in the study of Mas-Machado *et al.*, in 2015, the mean number of authors in studied articles had been increased from 2.13 in 2006 up to 2.28 in 2014 (the standard deviation was not calculated). In this study, it had been reported a relationship between the number of authors and the number of citation, so that the articles had been more cited by increasing the number of authors (11).

Current results showed that the first STROBE checklist guideline on how to write the title and abstract (mentioning to the type of study in the title or abstract) was observed in all articles and 100% of the studied articles mentioned to study type. In the study of

Pouralajal, *et al.*, investigating the quality of reporting the results of cohort studies in the journals of Lancet, JAMA, BMJ, New England Journal of Medicine, Annals of Internal Medicine and the Archives of Internal Medicine, 57 articles (95%) had mentioned to the study type in the title or the abstract (12). Hendriksma M, *et al.*, (2015) designed a study to compare the quality of reporting of observational studies in five Journals, including ear, nose and throat (Rhinology, Hearing Research (Hear Res), Ear and Hearing (Ear Hear), Head and Neck and Journal of the Association for Research in Otolaryngology (JARO) with 5 general medicine Journals of New England Journal of Medicine (NEJM), the Lancet, Journal of the American Medical Association (JAMA), British Medical Journal (BMJ) and PLOS Medicine (PLOS Med). This study reported that the quality of reporting in articles of general medical journals is better than ENT journals. They also stated that 55% of articles published in general medical journals and 48% of the articles published in ENT journals had mentioned to the study type in the title or abstract (13). Wang *et al.* designed a study to evaluate Quality analysis of observational studies on pelvic organ prolapse in China from January 1996 to December 2015. They reported that the reporting ratio of study design in all of the observational studies was 3.9% (15/386) (14). Since the articles in the present study were identified and investigated by searching the keyword of "case" and "control" in the title or keywords of articles indexed in the SID website, so there is a possibility that the number of case-control articles published in the database would be more than 120 articles over the period of 10 years, and some of these articles were not enrolled in the study because of lack of mentioning the study type in the title or abstract. Considering this possibility, the level of compliance with the first STROBE checklist guideline could not be 100% in this study.

The present study demonstrated the balance in writing of the different sections of the abstract in 78 studied articles (65.0 %), and proposal of "what was done and what was found" had been completely observed in the 69 articles (57.5%). Pouralajal *et al.* also reported the balance in the writing of abstract in 95% (57 cases) of their studied articles. They stated that the long-term study period and high costs of the cohort studies could be the reason for more accuracy in writing of this type of articles compared to case-control and descriptive studies (12). Hendriksma *et al.*, also claimed that this proposal had been observed in over 97% of cases (13).

Based on the STROBE checklist, the authors of case-

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control articles should present a scientific background of the subject and the objectives in the introduction section. These points were observed in respectively 115 (95.8%), and 109 (90.8%) articles out of the reviewed articles. The scientific background of the subject had been referred in all (100%) articles reviewed by Hendriksma *et al.*, (13). Pouralajal *et al.* reported that scientific background had been mentioned in all the reviewed cohort studies (100%). They also found that general objective has been noted in 91.7 % of articles (55 studies) and specific objectives have been presented in 60% of articles (36 studies). These researchers reviewed the cohort studies published in 6 prestigious international journals before issuing STROBE statement (12). The results of present study evaluating the case-control articles indexed in SID website indicated an acceptable quality of reporting in these articles.

In the present study, 105 (90.5%) articles had mentioned to the study type at the beginning of materials and methods section while this value was 70% (42 studies) in the study of Pouralajal *et al.*, (12). Given that the respective study was conducted before issuing the STROBE Statement, the improvement in the quality of reporting in the articles as the results of the present study is not unexpected.

The equality of evaluation methods for variables had been considered in 100% of the studied case-control articles, but in none of these articles, "the periods of exposure "and "how missing data were addressed" had been described. In addition, none of the studied articles had used the flowchart. Pouralajal *et al.* stated in their study that the duration of exposure had been determined in 43 articles (77%), and duration of follow-up in 58 studies (98%). They also reported that only 20 studies (33.3%) out of the reviewed articles had used the flowchart (12). In the study of Hendriksma *et al.*, flowchart had been used in 7% of articles published in ENT journals and 45% of articles published in medical journals (13). In the research of Wang, *et al.*, the reporting ratio of flow diagram was 0% (14).

In the STROBE checklist, 9 suggestions are presented to the authors to improve the quality of reporting the results of the case-control articles. The information of participants such as demographic, clinical and social characteristics is some of the cases that must be addressed at the beginning of the results. In the present study, this proposal was observed in 88 articles (75.9%) but "the number of participants with uncompleted data" as well as "summarized sizes or the number of exposure in each of the exposure groups" had been mentioned in only one case out of reviewed articles (0.9%). In the study of

Pouralajal *et al.*, it is reported that the demographic characteristics of subjects have been mentioned in 49 (81.7%) articles (12). Hendriksma M *et al.* stated that the number of participants with missing data was 45% of articles published in medical journals and 7% of articles published in ENT in their reviewed articles (13).

Based on STROBE Statement recommendations, the authors of case-control articles should mention the summary of the main findings of their study in the discussion section of the article. In the present study, it was determined that this suggestion was observed in 108 articles (93.1%) in the study period. However, the objectives of the study were not mentioned in the discussion section of 87 articles (75%). Direction and amount of possible bias were not also discussed in the 87 articles (75%). Pouralajal *et al.* stated in their study that in the 98.3% (59 studies) out of reviewed cohort articles, key results were written at the beginning of the discussion. They also reported that in 9 studies (15%), the limitations of study implementation and factors causing the bias in study results had not been discussed (12).

The source of funding and the role of funders as the last recommendation of this checklist were observed in 61 articles (52.6%) out of the reviewed articles. This value was 91.7% (55 studies) in the study of Pouralajal *et al.*, while Hendriksma *et al.*, stated that almost 80% of studies in ENT journals have not mentioned to the source of funding (13).

The quality of the reported case-control articles, indexed on the SID website during 2006 to 2015, was acceptable, but some of the items in this checklist still need more attention. Given that compliance with the STROBE statement guidelines increase the articles chance to be accepted in prestigious journals and so the obtained results will be available for more readers. The authors and reviewers should consider all recommendations of this checklist with more accuracy. It is essential that epidemiological studies be conducted in a better quality in developing countries, including Iran (15).

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