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Review Article

Application of Strengthening the Reporting of Observational Studies (STROBE) Statement Guideline in Nursing Studies: Analytical Review

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Abstract

Background: Strengthening the Reporting of Observational Studies in Epidemiology (STROBE) guidelines were created to aid the author in ensuring high-quality presentation of the conducted observational study. ***Objective***: Applying the STROBE statement guideline checklist to evaluate the quality of nursing studies and observational reporting. ***Methods***: Analytical review of literature based on previous studies and reviews derived from Scopus, PubMed, and Medline databases concerning STROBE statement guidelines. The data collection was conducted from December 2020, to April 2021. These studies were collected and filtered according to the specific criteria and used keywords such as STROBE, nursing studies, evidence-based nursing practice, cohort studies, case-control studies, cross-sectional and observational studies, as well as articles from the National Library of Medicine. ***Results***: Few papers have been published that demonstrate an appreciation of STROBE, but their descriptive features do not seem appropriate for nursing publications. In comparison to STROBE, relatively few papers mentioned primary sources or other information regarding the selection process for study participants and the observation time frame. ***Conclusion***: Despite the widespread availability of reporting guidelines in both medical and nursing fields, many researchers do not follow them.

Keywords: STROBE statement, Guideline, Observational Studies, Evidence-based nursing.

تطبيق المبادئ التوجيهية لتعزيز الإبلاغ عن الدراسات القائمة على الملاحظة في دراسات التمريض: مراجعة تحليلية

الخلاصة

الخلفية: تم إنشاء مبادئ توجيهية للإبلاغ عن الدراسات القائمة على الملاحظة في علم الأوبئة لمساعدة المؤلف في ضمان عرض عالي الجودة للدراسة القائمة على الملاحظة التي أجريت. **الهدف**: تطبيق قائمة مرجعية لإرشادات بيان STROBE لتقييم جودة دراسات التمريض والتقارير القائمة على الملاحظة. **الأساليب**: مراجعة تحليلية للدراسات والمراجعات السابقة المستمدة من قواعد بيانات Scopus و PubMed و Medline المتعلقة بإرشادات بيان STROBE تم جمع البيانات من ديسمبر 2020 إلى أبريل 2021 وتصفيتها وفقا لمعايير محددة واستخدمت كلمات رئيسية مثل STROBE، ودراسات التمريض، وممارسة التمريض القائمة على الأدلة، ودراسات الأتراب، ودراسات مراقبة الحالة، والدراسات المقطعية والرصدية، بالإضافة إلى مقالات من المكتبة الوطنية الأمريكية للطب. **النتائج**: تم نشر عدد قليل من الأوراق التي تظهر تقديرا ل STROBE، لكن سماتها الوصفية لا تبدو مناسبة لمنشورات التمريض، وبالمقارنة مع STROBE، ذكر عدد قليل نسبيا من الدراسات مصادر أولية أو معلومات أخرى تتعلق بعملية اختيار المشاركين في الدراسة والإطار الزمني للملاحظة. **الاستنتاج**: على الرغم من توافر إرشادات الإبلاغ على نطاق واسع في كل من المجالات الطبية والتمريضية، إلا أن العديد من الباحثين لا يتبعونها.

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INTRODUCTION

Too many observational studies are published without adhering to the STROBE statement's reporting guidelines. This can result in inaccurate findings and a loss of public confidence in research. Inadequate reporting impairs the assessment of a study's strengths and flaws, as well as the generalizability of its findings. Numerous nursing and health research concerns are investigated using observational studies, and the majority of research on illness etiology is conducted through case-control, cohort, or cross-sectional studies. Additionally, observational studies contribute to the understanding of the risks and benefits of nursing treatments. Randomized control trials (RCTs) are unable to address all critical questions about a particular intervention. For instance, observational studies are better appropriate for detecting late or uncommon adverse effects of treatment and demonstrating more than what was accomplished in routine nursing practice. In observational studies, researchers collect data on interesting traits and measures but have no control over events. The majority of surveys and epidemiological studies are observational in nature and may be prospective or retrospective. Numerous observational studies have been done to determine or explore the probable association between several factors and the development of an illness or condition. Generally, observational studies are used to examine variables or exposures over which the investigators have no control, such as employment or smoking habits [1]. However, publications based on observational studies frequently lack essential information or are ambiguous as a result of inadequate reporting of potential confounding variables, case-control procedures, and eligibility criteria. As a result, rules for reporting observational studies have been devised. Two groups developed the STROBE statement: one from Canada and another from Europe. These two groups intended to ensure that all parts of an observational study were accurately and objectively documented so that readers could make educated judgments regarding the findings' validity [2]. Strengthening the Reporting of Observational Studies in Epidemiology (STROBE) was founded in 2004 by a network of methodologists and researchers, as well as journal editors. The article Strengthening the Reporting of Observational Research in Epidemiology offers suggestions for the minimum information that should be included in the design of three types of observational studies: cohorts, case-control, and cross-sectional studies. A report bolstering an observational statement was published in eight journals alongside an explanation and elaboration article; the papers were published concurrently in three journals [3]. There is growing concern that a large proportion of nursing research is observational rather than randomized controlled trials. Without intervention, observational studies cannot establish causality, as interventions may have a confounding effect on the outcome measured in such investigations. Despite these limitations, observational study designs are regarded acceptable in nursing research since they are reasonably inexpensive and allow for the examination of long-term or large populations of individuals over an extended period of time (e.g., 20 years) [4]. Interventional designs can only provide evidence about the intervention's influence on an outcome, not on the causal relationship between the effect and the cause. Causal links may be established using prospective or experimental investigations, but they are not necessarily required. However, more rigorous design types may be better if the research objective is to gather knowledge about how to improve or enhance clinical practice (e.g., improving treatment procedures) or to establish new research institutions (e.g., new study designs, resources) [5]. The purpose of this study is to use the guideline checklist for Strengthening the Reporting of Observational Studies in Epidemiology (STROBE) and to analyze the quality of nursing studies observational trial reporting.

METHODS

To address these concerns, a detailed analytical assessment of papers published

between December 2020 and April 2021 was done. The researcher evaluated multiple types of literature in relation to the Strengthening the Reporting of Observational Studies in Epidemiology (STROBE) Statement Guideline, including past studies and reviews generated from worldwide publishers' databases such as (Scopus, PubMed, and Medline). These studies were identified and filtered using specific criteria, including STROBE, nursing studies, evidence-based nursing practice, cohort studies, case-control studies, cross-sectional and observational studies, as well as articles from the National Library of Medicine that contained valid and documented data from global research and epidemiology. Until now, only a few qualitative studies have been conducted to determine the extent to which reporting criteria are followed in nursing research. The paper provides an instructive overview but suffers from a dearth of empirical evidence.

RESULTS AND DISCUSSION

The STROBE statement provides recommendations on how observational research in nursing should be reported. The Center for Research-based Nursing Practice (CRNP) developed STROBE, which was endorsed by the American Nurses Association (ANA). Each year, the guidelines are modified. The guideline defines the many types of observational studies and, more importantly, provides suggestions on the most acceptable study designs for various goals. The STROBE statement is a reporting guideline that assists in categorizing research and provides guidelines on how to effectively report them [6]. In recent years, there has been considerable discussion about the significance of clearly reporting and presenting the results of observational studies in research articles in an objective and transparent manner. Yet, nothing is known regarding the relationship between adhering to any reporting rule and improved reporting quality. According to a 2011 study published in the Journal of Clinical Nursing, more than half of reviews published in major nursing journals did not follow the requirements established by the STROBE statement [4]. A group of investigators from several journals collaborated to improve the quality of studies. The researchers discovered that less than 50% adherence is prevalent in nursing research and stated that a rate of 75% or better should be the target in all scientific disciplines. Numerous studies have demonstrated that publications that employ strobe standardization have a higher level of reporting than those that do not. The Sword-CS study demonstrated that stroboscope statements increased the quality of reporting in ontological and audiological observational studies. Numerous stroboscopes were adequately described in a cross-sectional study published in the Korean Journal of Women's Health and Nursing. Two researchers independently assessed the included studies using the stroboscope statement, and disagreements were resolved through discussion [7]. For instance, imagine a case-control study of heart attacks and oral contraceptives is incorporated into a large pharmaceutical and epidemiological database that has information on thousands of women who could serve as controls. In that circumstance, researchers may be motivated to pair controls with individuals who share comparable risk factors for heart attack. In case-control studies, a rational choice must be made regarding the application of matching controls to case variables, either via a precise matching approach or through the use of an acceptable statistical analytic method. One goal is to adjust to circumstances that may affect the prescription of oral contraceptives and to eliminate ambiguous indications [8]. STROBE has not been substantially examined in nursing research to date. This results in a general lack of information regarding the proper application of the STROBE statement guideline in nursing research. Although no study has been conducted on the use of the STROBE statement guideline to nursing studies, this paper analyzes several research articles that have been published utilizing this guideline. The STROBE statement guideline strives to standardize and transparently disclose observational studies in nursing research. The STROBE statement offers writers with a checklist to help them minimize

bias and improve the quality of their research papers. The protocol verifies numerous critical components, including the study's design, data collecting, and analysis. This is all done to improve the quality of observational studies reported in nursing research. This guideline aims to promote the use of rigorous, reliable, and valid observational studies in nursing. Additionally, it includes suggestions on how to improve reporting when publishing these research in scientific journals, so that readers may understand for themselves the study methodology, analysis methodologies, and data collection strategies [9]. Although the STROBE statement 22-point checklist is not meant to judge the quality of research, it serves as a common framework for the standardized and rigorous reporting of observational research (Table 1). Numerous sections of the publication make reference to organizational structures. The STROBE guidelines urge that researchers document the number of participants in each study phase and the reasons for their exclusion. The record policy emphasizes the critical nature of reporting results that have been screened for data quality, availability, and linkage. STROBE records advocate the use of flow charts to illustrate the selection of study populations [10]. The reporting of such research is insufficient and impairs the assessment of its strengths and flaws, as well as the generalizability of findings. The STROBE statement's guidelines for presenting non-randomized data in research do not fully convey the complexities of pharmaco-epidemiologic research. The reporting on this research is frequently insufficient, obstructing examination of its strengths and faults and generalizability [11]. In order to make the review easier to understand, the STROBE's checklist has been divided into six sections, according to the components of the paper or parts of the article:

Context – what is the study about?

Design – what was the design?

Participants – who participated in this study?

Methodology – what were the method, and how were they done?

Results – what are the results and their significance?

Conclusion – does this finding change practice or policy either now or in the future?

The STROBE statement was updated in 2007 to "enhance the quality of observational study reporting, increase transparency in reporting, and allow for critical examination of study design, conduct, and analysis by others." This is critical because quality and transparency are critical guiding principles for health research, the findings of which can have a significant impact on clinical practice and health care provision. The STROBE statement was developed to improve the quality of observational research reporting by making recommendations for more transparent reporting methods and requiring a more thorough disclosure of study limitations [12]. As such, it possesses the features of a beneficial research instrument, enabling investigators and clinical nurses to conduct an observational study and reach an accurate conclusion based on the facts supplied [13]. Additionally, the researcher will be able to assess the observational research's overall quality and design. To aid in the review and make it more comprehensible, the STROBE checklist was separated into six pieces depending on the paper's components or sections.

Title and abstract **–** The title should be informative, indicate that the study is observational, be succinct and free of abbreviations. In the title and/or abstract, indicate that the study is observational in nature. The abstract should comprise the following sections: study topic, trial design, techniques, objectives, significant results or arguments, and conclusions.

Introduction **–** It provides scientific context, a concise assessment of the literature, piques curiosity, and explains the rationale for the presented study (Is causality between exposure and outcome plausible? Justify why this study design is the most effective

Table 1: STROBE Statement checklist of information that should be included in reports of observational studies (Cohort/Cross-sectional and case-control studies)

Section/Topic	Item No	Recommendation
Title and abstract	1a	"Indicate the study's design with a commonly used term in the title or the abstract"
	1b	"Provide in the abstract an informative and balanced summary of what was done and what was found"
Introduction		
Background/rationale	2	"Explain the scientific background and rationale for the investigation being reported"
Objectives	3	"State specific objectives, including any pre-specified hypotheses"
Methods		
Study design	4	"Present key elements of study design early in the paper"
Setting	5	"Describe the setting, locations, and relevant dates, including periods of recruitment, exposure, follow-up, and data collection"
Participants	6a	***Cohort study***- "Give the eligibility criteria, and the sources and methods of selection of participants. Describe methods of follow-up"
	6b	***Case-control study***- "Give the eligibility criteria, and the sources and methods of case ascertainment and control selection. Give the rationale for the choice of cases and controls"
	6c	***Cross-sectional study***- "Give the eligibility criteria, and the sources and methods of selection of participants"
Variables	7	"Clearly define all outcomes, exposures, predictors, potential confounders, and effect modifiers. Give diagnostic criteria, if applicable"
Data sources/ measurement	8*	"For each variable of interest, give sources of data and details of methods of assessment (measurement)".
Bias	9	"Describe any efforts to address potential sources of bias"
Study size	10	"Explain how the study size was arrived at (if applicable)"
Quantitative variables	11	"Explain how quantitative variables were handled in the analyses. If applicable, describe which groupings were chosen and why"
Statistical methods	12a	"Describe all statistical methods, including those used to control for confounding"
		Describe any methods used to examine subgroups and interactions
	12b	"Explain how missing data were addressed"
	12c	***Cohort study***- "If applicable, explain how loss to follow-up was addressed"
	12d	***Case-control study***- "If applicable, explain how matching of cases and controls was addressed"
	12e	***Cross-sectional study***- "If applicable, describe analytical methods taking account of sampling strategy"
		"Describe any sensitivity analyses"
Results		
Participants	13*	"Report numbers of individuals at each stage of study e.g., numbers potentially eligible, examined for eligibility, confirmed eligible, included in the study, completing follow-up, and analysed"
		"Use of a flow diagram"
Descriptive data	14a*	"Give characteristics of study participants (e.g., demographic, clinical, social) and information on exposures and potential confounders"
	14b	"Indicate number of participants with missing data for each variable of interest"
	14c	***Cohort study***- "summarize follow-up time (e.g., average and total amount)"
Outcome data	15a*	***Cohort study***- "Report numbers of outcome events or summary measures over time"
	15b	
	15c	***Case-control study***- "Report numbers in each exposure category, or summary measures of exposure"
		Cross-sectional study- "Report numbers of outcome events or summary measures"
Main results	16	"Give unadjusted estimates and, if applicable, confounder-adjusted estimates and their precision (e.g., 95% confidence interval). Make clear which confounders were adjusted for and why they were included"
Other analyses	17	"Report other analyses done- e.g., analyses of subgroups and interactions, and sensitivity analyses"
Discussion		
Key results	18	"summarize key results with reference to study objectives"
Limitations	19	"Discuss limitations of the study, taking into account sources of potential bias or imprecision. Discuss both direction and magnitude of any potential bias"

Interpretation	20	"Give a cautious overall interpretation of results considering objectives, limitations, multiplicity of analyses, results from similar studies, and other relevant evidence"
Generalizability	21	Discuss the generalizability (external validity) of the study results
Other information		
Funding	22	Give the source of funding and the role of the funders for the present study and, if applicable, for the original study on which the present article is based

* "Give information separately for cases and controls in case-control studies and, if applicable, for exposed and unexposed groups in a cohort and cross-sectional studies". **Note:** "An explanation and elaboration article discusses each checklist item and gives methodological background and published examples of transparent reporting. The STROBE checklist is best used in conjunction with this article (freely available at http://www.plosmedicine.org/, and at http://www.epidem.com/). Information on the STROBE Initiative is available at www.strobe-statement.org."

technique for addressing the research issue. The state's precise aims must be stated clearly and objectively, along with any predefined causal hypotheses (if any), all of which must be articulated in a clear and objective manner.

Methods **–** Comprehensive overview and explanation of the observational methods employed. It should explain what it did and how it did it, and it should do it in the following manner: Consider providing tables of data sources for all stages of research in the study design and data sources sections of the paper. At the bottom of each source of data that contributes to the analysis, describe the study's design and the research population, which was chosen for obvious reasons. Additionally, describe the locations, settings, and pertinent data, including recruiting periods, exposure, monitoring, and data collection times, as well as the location of the data collection, if available. Describe the eligibility criteria, sources, and procedures used to choose and enroll participants, along with an explanation of why these criteria were chosen. Justify the sample size chosen for analysis and provide the computed sample size. Describe the variants' measurement, quality, and selection. We offer evaluation methodologies and diagnostic criteria for diseases for each exposure, outcome, and other important factors. If necessary, obtain the Ethics Committee's clearance and the participants' informed consent. These are hypotheses that explicitly explain all of the analysis's major assumptions (e.g., relevance, exclusion, independence, and consistency) as well as any additional or sensitive analysis assumptions. The term "assumption assessment" refers to the procedures used to examine or defend the validity of assumptions. Additionally, the analysis discusses statistical approaches that outline proper statistical methods for analysis and the statistics employed in the study. (that is, the scale, the units, and the model). Describe the process of identifying the variants and weights that will be used in the analysis (i.e., model and independence). Take a look at a flow chart. Describe how the missing data were accounted for and, if appropriate, how multiple testing was handled. Finally, the software and pre-registration sections indicate the name of the statistical software, its version and settings, as well as whether the study protocol and sufficient details were pre-registered, allowing for re-procedure findings (as well as where and when).

Results – Report the number of persons included in each study phase and the reasons for their exclusion in descriptive data. Consider utilizing a flow chart. The experimental exposure, outcome(s), and other related variables are summarized statistically (e.g., mean, standard deviation, proportion). If the data source contains a meta-analysis of earlier studies, provide the number of studies, their ancestors, if available, and an assessment of study heterogeneity. Provide information about the similarities between a variant exposure sample and an outcome, as well as the amount to which the sample overlaps with the source of exposure. Report the association between the variation and the exposure and the variant and the outcome in the main results section, preferably on an interpretive scale. The authors present estimates of the causal effect between exposure and outcome, as well as the associated uncertainty measures. For standard deviation differences, use intuitive measures such as odds ratios or relative risks.

Periods of follow-up; recruiting periods; statistical methodologies and estimated effect sizes utilized to acquire primary and secondary outcome values; and outcomes such as confidence intervals (95%) should all be given.

Discussion – It outlines the study's major findings in relation to the study's aims. Discuss the limitations of the study, taking into account the validity of the assumptions and other possible sources of bias and mistakes in the methodology. Discuss the direction and magnitude of any potential bias, as well as any attempts to eliminate it. Provide an overall assessment of the data, weighing the benefits and drawbacks while taking into account the objectives and constraints. They discuss if the results are clinically or statistically significant and whether the intervention has the same effect when compared to other relevant evidence and research. Distinguish whether the findings are therapeutically meaningful or relevant, and whether the impact of interventions can be of comparable magnitude. Discuss the study's generalizability and applicability to other groups (e.g., external validity), alternate exposure periods and time frames, and alternative exposure levels.

Other important information – The observational study must be registered and include the registry's name and registration number; it must make the complete study protocol available; it must include the sources of funding and various types of support; and it must emphasize the role of the funders in the current study and, if applicable, in the original study or studies upon which the current article is based. All analysis and reporting locations and data access techniques are based on current data. Where is the statistical code, if it is open to the public? Each author is required to disclose any potential conflicts of interest. Along with the checklist, registration, assignment, follow-up, and analysis of patients included in the observational study, the STROBE statement contains a flow chart that instructs the reader on how to conduct the study. Most notably, clinical nurses should analyze the availability and quality of flow charts in the observational study under review, as they provide a high-level overview of the study's methodology and provide a concise report on the approach utilized.

Conclusion

The purpose of Strengthening and Reporting Observational Studies Statements is to provide useful advice for reporting epidemiological observational studies. Effective reporting showed the study's limitations and strengths, facilitating the study and assisting in the interpretation and application of the study's findings. Additionally, the STROBE statement can aid in the planning of observational studies and serve as a guide for peer reviewers and editors when evaluating articles. Recent studies indicate that the STROBS statement is not being heeded nearly as frequently as it should. The study's findings indicate that, despite broad availability of reporting rules in the medical and nursing areas, many researchers fail to adhere to them.

Recommendation

Extensive reporting is a necessary component of excellent research. If statistics, techniques, and findings are not described adequately, they might be difficult to comprehend. The principles assist researchers in producing an orderly and well-organized piece of work. The guidelines are simple to follow. Making work appear professional demonstrates that researchers are committed to the study. To improve the quality and transparency of nursing observation studies reporting, researchers should adhere to the STROBE statement guidelines while planning or submitting research. To ensure the trustworthiness of observational studies, researchers must follow guidelines that outline specific stages and methods. Utilize appropriate checklists for reporting, such as Consolidated Standards of Reporting Trials (CONSORT), and STROBE [13].

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Conflicts of interest

The author declares no conflict of interest.

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