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Original Research Article

Assessment of Adherence of Observational Studies to STROBE Statement

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Abstract:

Introduction: The quality of biomedical research's methodology and reporting has received a lot of attention. There is a growing incentive to publish rather than for the advancement of science leading to increased deficiency in the quality of reporting medical research. Strengthening the Reporting of Observational Studies in Epidemiology (STROBE) is a checklist of elements developed by professionals to improve consistent and thorough reporting of observational studies. The current study looked at the adherence of observational studies to STROBE statement.

Methods: Five open access Indian journals from various specialties, that were published between 2016 and 2022 were chosen and reviewed by authors who assigned “yes", "partially", or "no” to whether the STROBE criteria were followed. Additionally, we also assessed was the completeness of reporting across the three major study designs and journals and data was analyzed using descriptive statistics.

Results: A total of 235 articles were assessed. Ninety percent of the papers met criteria such as those for the title and abstract, background, objectives key findings, study settings, and outcome data. Items including bias, sample size, flow diagrams, and missing data have adherence rates of less than 30%. The overall mean completeness of reporting (COR) was found to be 60.97±14.51%. The COR for cohort, case-control and cross-sectional studies was 73.83 ± 12.17 %, 48.73 ± 12.75% and 61.44 ± 14.46% respectively.

Conclusions: The overall reporting was inadequate. Hence more journals should endorse the STROBE checklist and make sure those authors and reviewers comply with it.

Keywords: Cross-Sectional, Cohort, Case-Control, Research Methodology, Sample Size.

Introduction

Clinical research is a systematic approach that enables medical practitioners to investigate and produce new data. It is also a crucial element in determining the future views in medical science. A thirst for knowledge is a must to stay updated in one’s field.

Clinicians today adhere to the philosophy of Evidence-based medicine (EBM), which is based on reliable data. The two main approaches in medical research that a clinician relies on are observational studies and randomised control trials (RCT).[1] Though RCTs are considered superior experimental designs, the complexity of the study design and the need for rigorous conduct led researchers to favor the observational designs. [2]

In clinical speciality publications, 6–9 out of every 10 articles are observational studies (cross-sectional, cohort, case-control).[2] The conduct of observational designs is quick, simple, and affordable.[3] Additionally, they provide a greater degree of external validity as it is simple to extrapolate the findings to the entire population; nevertheless, the internal validity is hampered by bias and various confounders.[4] Studies on rare disease or rare outcome are more feasible with observational design than RCT.[5]

Good research has the greatest potential to generate proof when only presented as early as possible. There has been a recent increase in the number of scientific journals and issues published.[6] Unfortunately, the idea of "publish or perish" has had a negative impact on medical research.[7] This resulted in the published research being less transparent, leaving out key material, or having a serious methodology defect that limited the generalizability of the findings.[8]

The mandatory publication requirements by the medical regulatory authorities for academic positions have compelled the authors to find easy shortcuts to publish their work.[9] The mediocre quality of the publication continues to be a problem, particularly in middle-income nations.[10] Quality control with appropriate guidelines for reporting is the need of the hour to overcome these poor

standards.[10] These guidelines guarantee a high-quality publication and clearly communicate to the readers what was intended (and what wasn't), what was actually done, what was discovered, and what the findings indicate. [10] A 22-item checklist called "Strengthening the Reporting of Observational Studies in Epidemiology" (STROBE) Statement was developed in order to present the paper in a more appealing and intriguing manner.[11] It comprises items related to the title and abstract, introduction, methods, results, discussion and other information. [11]

The purpose of the current study was to evaluate how closely observational studies that were published in Indian journals complied with the STROBE criteria.

Materials and Methods:

Study was initiated after obtaining exemption (IEC/66/22) from the Institutional Ethics committee. Five Indian PubMed index journals were chosen for this study that was available in public domain to assess how closely observational studies adhered to the STROBE criteria. These included: Indian Journal of Pharmacology, Indian Journal of Pathology and Microbiology, Indian Journal of Dermatology Venereology and Leprology, Indian Journal of Ophthalmology and Indian Journal of Pediatrics.

Only observational studies were included in the final analysis of all research articles published in these chosen journals between January 2016 and July 2022. Review articles, RCTs, lectures, special contributions, seminars, training and education, summaries of domestic and foreign theses, research topic announcements, letter to editor, posters, animal studies, genetic linkage studies, infectious disease modelling, case reports and case series were excluded.

The selected observational studies were classified into case control, cohort and cross-sectional studies. Adherence of the articles to the items in STROBE checklist was reviewed by two reviewers. The research team evaluated the chosen papers based on how closely they adhered to the STROBE declaration.

The checklist was used to assess adherence by checking "YES" for items that were adequately described, "PARTLY" for those that were only partially detailed, and "NO" for those that were not covered at all. In case of any discrepancies in the assessment between the two reviewers, an additional review was then conducted independently, and the consensus was taken as the final decision. The percentage of articles that met the STROBE checklist was then determined. The completeness of reporting was evaluated using the formula (Yes/ Yes+Partly+No) x 100 for each article.[12]

Statistical analysis:

Data was entered in Microsoft Excel and analyzed using descriptive statistics. Parametric quantitative variables were expressed as mean ± standard deviation and qualitative variables were expressed as absolute and relative frequencies.

Results:

The overall number of research articles that were published in the selected five journals between January 2016 to July 2022 was about 11418. Out of which, 235 articles satisfying the inclusion-exclusion criteria were selected and categorized into cross-sectional, cohort and case control studies. (Fig.1)

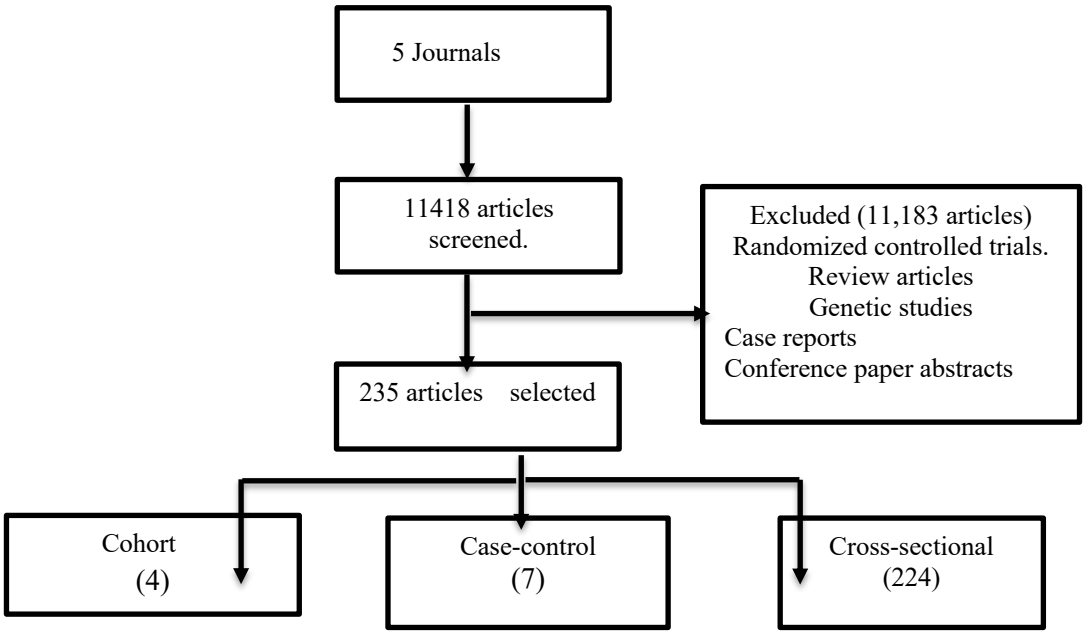

Figure 1: Selection and Categorization of articles

The adherence of all the articles selected to the individual items in the STROBE guideline is represented in Table No: 1. Adherence to STROBE statement by various study designs has summarized in Table No: 2.

Table 1: STROBE Statement adherence to all the articles (n=235)

	Item number	Recommendation	Yes n (%)	Partly n (%)	No n (%)	NA n (%)
Title and abstract	(1)	a)	181(77.02)	10 (4.25)	44 (18.72)	-
		b)	220 (93.6)	11 (4.68)	4 (1.7)	-
Introduction	Background/ rationale (2)	a)	214(91.06)	19 (8.08)	2 (0.85)	-
	Objectives (3)	b)	216(91.91)	13 (5.53)	6 (2.55)	-
Methods	Study design (4)	a)	213(90.63)	8 (3.40)	14 (5.95)	-
	Setting (5)	b)	178(75.74)	41 (17.44)	16 (6.8)	-
	Participants (6)	a)	209(88.94)	18 (7.66)	8 (3.4)	-
		b)	8 (3.4)	0 (0)	3 (1.28)	224(95.32)
	Variables (7)	a)	185(78.72)	23 (9.79)	27 (11.49)	-
	Data sources/ measurement (8)	a)	197(83.83)	14 (5.96)	24 (10.21)	-
	Bias (9)	a)	52 (22.13)	7 (2.98)	176 (74.9)	-
	Study size (10)	Study size	65 (27.66)	1 (0.42)	169(71.91)	-
	Quantitative variables (11)	Quantitative variables	188 (80)	11 (4.69)	31 (13.2)	5 (2.13)
	Statistical methods (12)	a)	186(79.15)	6 (2.56)	43 (18.3)	-
		b)	157 (66.8)	7 (2.98)	50 (21.28)	21 (8.94)
		c)	19 (8.09)	0 (0)	162(68.94)	54 (22.98)
		d)	107(45.53)	2 (0.85)	78 (33.19)	48 (20.4)
		e)	87 (37.02)	6 (2.55)	85 (36.17)	57 (24.25)
Results	Participants (13)	a)	197(83.82)	10 (4.25)	28 (11.9)	-
		b)	42 (17.87)	4 (1.70)	134(57.02)	-
		c)	13 (5.53)	1 (0.42)	221(94.04)	-
	Descriptive data (14)	a)	206(87.65)	13 (5.53)	16 (6.8)	-
		b)	46 (19.57)	65 (27.65)	124(52.76)	-
		c)	4 (1.70)	-	231(98.29)	-
	Outcome data (15)	a)	227(96.59)	2 (0.85)	6 (2.55)	-
	Main results (16)	a)	119(50.63)	6 (2.55)	52 (22.13)	58 (24.68)
		b)	115(48.93)	47 (20)	73 (31.06)	-
		c)	13 (5.53)	3 (1.28)	119(50.63)	100(42.5)
	Other analysis (17)	a)	161 (68.5)	4 (1.7)	47 (20)	23 (9.79)
Discussion	Key results (18)		217(92.34)	11 (4.69)	7 (2.98)	-
	Limitations (19)		185(78.72)	6 (2.55)	44 (18.72)	-
	Interpretation (20)		207(88.09)	20 (8.51)	8 (3.4)	-
	Generalizability (21)		187(79.57)	22 (9.36)	26 (11.06)	-
Other information	Funding (22)		227 (96.6)	-	8 (3.4)	-

Table 2: STROBE Statement adherence of all the articles according to the type of study design

	Item No.	Recommendation	Cross-sectional (%) N=224				Cohort (%) N=4				Case-control (%) N=7			
			Yes	No	Partly	NA	Yes	No	Partly	NA	Yes	No	Partly	NA
Title and abstract	1	a)	77.2	17.4	5.6	0	100	0	0	0	57.14	42.86	0	0
		b)	94.2	1.3	4.46	0	75	25	0	0	85.7	0	14.29	0
Introduction	2	Background/ rationale	90.6	0.9	8.5	0	100	0	0	0	100	0	0	0
	3	Objectives	91.5	2.7	5.8	0	100	0	0	0	100	0	0	0
Methods	4	Study design	91.1	4.9	4	0	75	25	0	0	71.4	14.3	14.3	0
	5	Settings	76.8	6.3	16.9	0	75	25	0	0	28.6	14.3	57.1	0
Participants	6	a)	88.8	3.6	7.6	0	100	0	0	0	71.4	0	28.6	0
		b)	0	0	0	100	50	50	0	0	42.9	28.6	14.3	14.3
	7	Variables	79.9	9.8	10.3	0	75	25	0	0	42.9	28.6	28.6	0
	8	Data sources/ measurement	83.5	10.3	6.2	0	75	25	0	0	85.7	0	14.3	0
	9	Bias	22.3	72.8	4.9	0	25	75	0	0	14.3	85.7	0	0
	10	Study size	27.7	71.4	0.9	0	50	50	0	0	14.3	85.7	0	0
	11	Quantitative variables	81.2	12.1	6.7	0	75	25	0	0	42.9	42.9	14.3	0
Statistical methods	12	a)	79.9	15.6	4.5	0	50	50	0	0	57.1	14.3	14.3	0
		b)	65.2	21.9	12.9	0	75	25	0	0	100	0	0	0
		c)	8.5	68.7	22.8	0	0	50	0	50	0	85.7	0	14.3
		d)	47.3	30.6	21.9	0	0	75	0	25	14.3	85.7	0	0
		e)	37.5	35.7	26.8	0	25	25	0	50	0	100	0	0
Results Participants	13	a)	86.1	8.5	5.4	0	50	25	25	0	28.6	42.9	14.3	14.3
		b)	17.9	82.1	0	0	25	50	0	25	14.3	85.7	0	0
		c)	5.8	93.7	0.5	0	0	100	0	0	0	85.7	0	14.3
Descriptive data	14	a)	88.9	5.3	5.8	0	50	25	25	0	57.1	42.9	0	0
		b)	19.6	51.8	2.7	25.9	25	50	0	25	14.3	85.7	0	0
		c)	0	0	0	100	25	25	0	50	14.3	14.3	0	71.4

Outcome data	15		98.2	0.5	1.3	0	75	25	0	0	71.4	0	14.3	14.3
Main results	16	a)	52.2	20.5	2.3	25	50	0	0	50	28.6	57.1	14.3	0
		b)	49.1	31.7	3.2	16	50	0	0	50	42.9	28.6	14.3	14.3
		c)	5.4	93.8	0.8	0	0	50	0	50	14.3	42.9	14.3	28.6
	17	Other analysis	68.6	20.5	10.7	0	50	0	0	50	71.4	14.3	0	14.3
Discussion	18	Key results	92.9	2.7	4.4	0	100	0	0	0	71.4	14.3	14.3	0
	19	Limitations	79.4	17.4	3.2	0	75	25	0	0	42.9	57.1	0	0
	20	Interpretation	88.4	2.7	8.9	0	100	0	0	0	71.4	14.3	14.3	0
	21	Generalisability	80.8	9.4	9.8	0	50	25	25	0	57.1	14.3	28.6	0
Other information	22	Funding	96.4	3.6	0	0	100	0	0	0	100	0	0	0

Completeness of Reporting (COR)

The overall mean COR was found to be 60.97±14.51%. The COR for cohort, case-control and cross-sectional studies was 73.83 ± 12.17 %, 48.73 ± 12.75% and 61.44 ± 14.46% respectively.

The COR was also calculated for each journal, and it was found to be 35.76 ± 9.93% for Indian Journal of Pathology and Microbiology ,67.60 ± 9.88 % for Indian Journal of Ophthalmology, 57.64 ± 12.99 % for Indian Journal of Dermatology Venereology and Leprology, 50.36 ± 7.51 % for Indian Journal of Pharmacology and 48.59 ± 7.91 % for Indian Journal of Paediatrics.

Discussion:

In this retrospective study, we assessed the adherence of observational studies published in five Indian PubMed- indexed journals to the STROBE statement. The STROBE statement was developed to enhance reporting and promote critical evaluation of observational studies. [11]

The title of any manuscript serves as the reader's initial introduction to and impression of the published work. [13] Also, a properly structured title draws readers in, effectively summarizes the material in your manuscript, and encourages them to read more.[13] In our study, more than 70% of adherence to strobe guidelines is seen with respect to title.

The methodology in the article defines the steps that were taken during the research process, and it is the responsibility of an author to write in-depth information regarding the study's procedures.[14] This enables the readers to evaluate the study's credibility and reliability. [14] Likewise, all the potential sources and steps taken to handle bias should be disclosed by the author, enabling the readers to critically evaluate the scientific literature and engage in evidence-based medicine.[15]

Research bias can occur anytime when the research is being conducted and it systematically deviates the study's result from its true value. [15] Bero quoted “lack of reporting bias can make the findings more reasonable than they actually are”.[16] Due to scientific and ethical considerations, it is crucial to report the sample size in clinical research. It aids in determining the statistical power of the study and provides conclusive results.[17] Our study highlighted that >70% of the studies included a detailed report on the study's design, eligibility criteria, variables, and data source. However, there were concerns with the reporting of statistical techniques, bias, and the estimation of the sample size. According to a study by Charles P. et al., only 34% of studies in high-impact medical journals provided the sample size calculation.[18] Numerous scientific studies have revealed instances of poor reporting and performance of statistical analyses.[19 - 22] The authors' omission to disclose what has been done raises the possibility that they are unaware of the statistical methods applied to their data.[23] These critical methodological shortcomings reveal a need for betterment in the quality of documentation of the tools employed in the conduct of the study.

The current study has found higher levels of adherence (more than 80% of the studies) to STROBE guidelines with respect to the number of participants at each stage, demographic data of the participants and number of outcome events. Specifically in the result sections, the most under-reported items were flow diagrams, reasons for non-participation, and missing data. These items are often ignored by the writers. Similar findings were seen in a study conducted by Nagarajan VB et al. The adherence to bias, subgroup analysis, addressing missing data, sensitivity analysis, reason for non- participation, flow diagram, missing data was less than 30%.[24]

To determine whether the research population is an accurate representation of the target population and whether bias was introduced, it is essential to report the reasons for non-participation.[8] A well-structured flow diagram aids in effectively conveying the results concisely by including the number of participants in each stage and the key results obtained.[25] The findings of the study by Rahmani N. et al. were consistent with those of our research, which revealed that less than a quarter of studies mentioned the reporting of flow diagrams and sources of bias.[26] Observational studies frequently have missing data. Even though the issue of missing data is ubiquitous and crucial, only a few articles go into detail about it. Similar findings were

also reported in a review by Amalia Karahalios et al., highlighting the inconsistent reporting of missing data in cohort studies.[27] Authors should be encouraged to use online supplements to publish the details of the missing data in their study as well as the measures taken to deal with it because failure to disclose missing data can lead to bias.[27] Additionally, if missing data are adequately presented, the readers will be able to assess the validity of the results.[27]

The items under the discussion section are adequately presented in most of the studies (> 80%). This could be attributed to the mandatory submission criteria endorsed by the journals.

Limitations:

The period from which the articles were chosen was fixed arbitrarily between 2016 and 2022. Only 5 specialty journals were selected for evaluation and final analysis.

Recommendations:

- Enhancing the awareness regarding the importance of compliance with STROBE statements.
- Conducting workshops to train the researchers to draft manuscripts in accordance with the STROBE statement.
- Mandatory endorsement of STROBE statement in the journal author instructions.

Conclusion

The overall compliance of articles to STROBE statement was suboptimal. Items such as bias, sample size, flow diagram, missing data had less than 30% adherence. 90% of the publications complied with some of the requirements, including those for the tile and abstract, background, objectives, key findings, study settings, and outcome data.

The adherence to STROBE statements greatly improves the quality of observational study reporting and aids in the decision-making process for when and what new investigations are required. If authors and journals adopt the STROBE statement, reporting could become more transparent and enhance the completeness of the reporting. Therefore, more journals ought to adopt the STROBE checklist and make sure that both authors and reviewers adhere to it.

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