

ORIGINAL ARTICLE

Adherence of Observational Studies Published in Indian Journals to STROBE Statement

Vetrivel Babu Nagarajan¹, Shruti Bhide^{2*}, Hemant R Kanase¹, Anirudha Vyankatesh Potey³, Firoz Tadavi⁴

Abstract

Purpose/Aim: Quality of reporting is very important in medical research. To ensure a uniform and detailed reporting of observational studies experts came out with a checklist of items, named 'Strengthening the Reporting of Observational Studies in Epidemiology' (STROBE). The present study examines the adherence of observational studies published in selected Indian journals from 2011-2015 to STROBE Statement.

Methods: 7 open access Indian journals, belonging to different specialities were selected. All the observational studies were assessed by 5 independent reviewers for the adherence to STROBE checklist as 'yes, partly and no'. The completeness of reporting was also assessed.

Results: A total of 271 articles were examined. Only 10 items (Abstract, Background/rationale, Objectives, Study Setting, Data sources/ measurement, Quantitative variables, number of Participants at each stage, Characteristics of study participants, Key results) out of the 22 items and their subdivisions of STROBE were adhered to, in more than 70% of articles. Other 10 items (bias, subgroup analysis, addressing missing data, sensitivity analysis, reason for non-participation, flow diagram, missing data) had adherence in less than 30% of the articles. The completeness of reporting was 50.5%, 49.12% and 43.06% in cross sectional, cohort and case control study, respectively.

Conclusion: The overall reporting was suboptimal. The completeness of reporting did not differ in the three types of observational study designs.

Introduction

Over the years the number of scientific articles published across various fields have increased. These articles aim to promote the scientific understanding and health care. Quality of reporting is very important in medical research. Poor reporting of the studies may lead to poor assessment of the scientific research and misinterpretation of the results of the study.^{1,2} To ensure this, various guidelines were developed by experts like the CONSORT for Randomized Control Trials, PRISMA for systematic reviews and meta-analysis, STARD for Diagnostic Studies, and STROBE (Strengthening the Reporting of Observational Studies in Epidemiology) for observational studies.^{1,2} Studies have shown that 9 out of 10 articles published in clinical speciality journals

are observational studies.³ To ensure a uniform and detailed reporting of observational studies, STROBE statement was introduced in 2007.⁴ The STROBE statement has 22 items which detail and guide the authors reporting of various parts of the article like title and abstract, introduction, methods, results and discussion.⁵ Many journals recommend adherence to the STROBE statement to improve the quality and completeness of reporting observational studies. There is a lack of assessment of quality of reporting of observational studies in Indian journals. Hence, we decided to assess the reporting of the observational studies published in some Indian journals dealing with

different specialities in accordance with the strobe statement.

Methodology

We selected 7 Indian journals that are available in public domain belonging to the following specialities dermatology, anaesthesia, pharmacology, rheumatology and chest medicine. Study was initiated after obtaining exemption (EC/OA-166/2016) from the Institutional Ethics committee.

All original research articles published in the selected journals between 2011- 2015 were screened and observational studies were included for analysis. Review articles, RCTs, lectures, special contributions, case reports, seminars, training and education, summaries of domestic and foreign theses, research topic announcements, posters and animal studies were excluded. Genetic linkage studies, infectious disease modelling or case reports and case series as STROBE recommendations do not specifically address topics and they 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 were reviewed by two reviewers. The checklist was marked 'yes' if the item was described well, 'partly' if described partially, and 'no' if not addressed at all. In case of any discrepancies between the two reviewers, all the authors reviewed independently and the consensus was taken as the final decision. The percentage of articles complying with the STROBE checklist were calculated. The completeness of reporting was assessed using the formula (Yes/

¹Post Graduate Resident, ²Associate Professor, ³Specialty Medical Officer, ⁴Assistant Professor, Department of Pharmacology and Therapeutics, Seth GS Medical College, KEM Hospital, Mumbai, Maharashtra; *Corresponding Author
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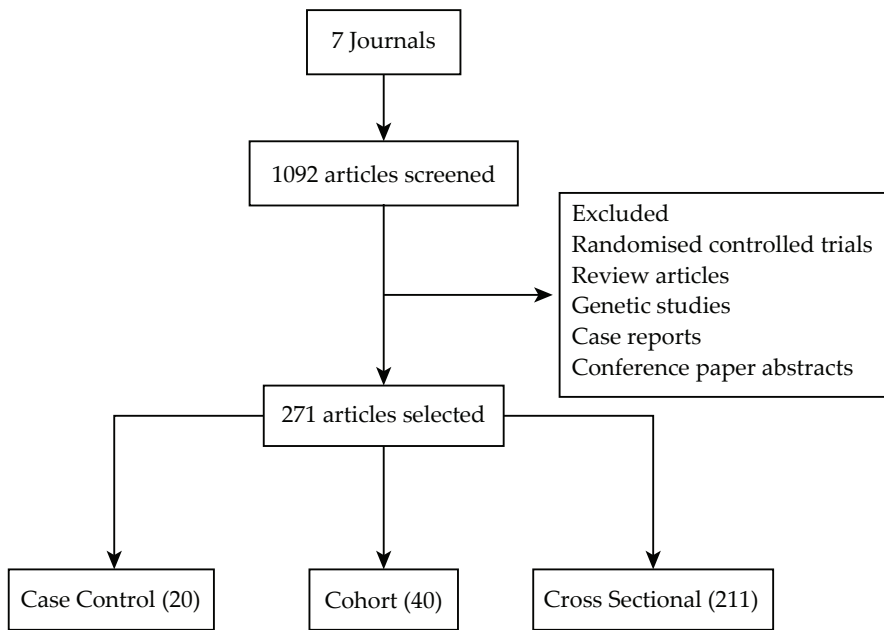


Fig. 1: Selection and categorization of articles

Yes+Partly+No) $\times 100$ for each article.⁶

Statistics

Data was entered in Microsoft excel sheet and was analysed using GraphPad Instat software version 3.06. Descriptive statistics were represented as percentages. The completeness of reporting was compared between different observational study designs using Kruskal Wallis test.

Results

After screening 1092 articles from the 7 journals published between the years 2010 to 2015, 271 articles were selected and categorized into cross sectional, cohort and case control studies (Figure 1).

The adherence of all articles to the individual items of STROBE is given in Table 1.

The adherence of the articles according to the type of study designs is given in Table 2.

The overall mean Completeness of Reporting (COR) was $49.86 \pm 13.46\%$. According to type of study design, the COR for cross sectional studies was $50.5 \pm 12.15\%$ for cohort studies was $49.11 \pm 17.54\%$ and for case control studies was $44.39 \pm 16.34\%$. The COR score of between the different study designs did not differ significantly ($p = 0.1460$).

Discussion

In the present study, most commonly reported items (>70%) were background

and objectives, settings, outcome, key results and interpretation. Items with low reporting (< 30%) were bias, sample size calculation, flow diagrams and addressing the missing data. Study design, study size, statistical methods used, limitations of the study, generalisability of the study and funding were adhered in 30-70% of the article. These findings were similar across all three categories of observational studies.

Few studies have assessed the compliance of articles with STROBE in different specialities. Langan et al⁷ observed that dermatology journals had low reporting regarding sample size calculations (7%), missing data (6%), losses to follow-up (12%), and statistical methods (14%) and the source of funding (9%). Kim et al⁸ observed poor reporting in case control and cohort studies published in Korean Journal of Family Medicine regarding study designs (10%), bias (13%) and study size (0%). Similar findings were noted in the present study.

Titles have a major impact on the article citations. Several factors like length of the title and presence and absence of certain words decide the impact and citation of the article.⁹ As per STROBE statement, the type of the study should be mentioned in the title. Although this might not help much in the overall narrative of the article,¹⁰ it helps in the ease of identification by the readers and indexing in digital

libraries.⁴ In the current study, only 19% of the studies mentioned about the type of study in the title. Only 15% of the articles mentioned the type of the study in the title in case control and cohort studies published in Korean Journal of Family Medicine⁸ while that in dermatology journals, it was 87%.⁷

Skipping the type of study in title may not impact the interpretation of the study much but not explaining the type of study and key elements in the body of the article will affect the reporting quality of the study. This puts readers at a disadvantage in identifying the type of study and affects the overall comprehensibility. STROBE recommends the authors to mention the type of study clearly as case control, cohort or cross sectional.⁴ In current study, only 50 % of articles mentioned type of study, while in dermatology journals, reporting was high about 70%.⁷

The trend of not reporting the bias is uniform across the journals. In majority of articles the issue of bias and ways to address bias was not handled adequately. Not reporting bias can alter the conclusions and hence the interpretations of the results of the study. Bero quotes that "*lack of reporting bias can make the findings more reasonable than they actually are*".¹¹ In current study, only 12% articles mentioned bias and the ways to address the bias. Comparable results were reported by Sorenson et al¹² (3%) in observational studies describing hand surgery and Kim et al⁸ (13%) in articles of Korean Journal of Family Medicine, while Langan et al⁷ reported a little higher percentage of reporting bias (31%). Researchers should report the identified potential sources of bias to make the reporting comprehensive for the readers.

STROBE mandates the authors to detail method of determining the sample size.⁴ Reporting sample size helps the readers to make their own decisions on whether the associations were really significant or by chance. Mentioning only the number of patients recruited for the study may leave the reader perplexed about the adequacy of the sample size. 34% of articles in this study reported how the study size was obtained. Comparing this with other studies, 4.5% in dermatology journals,⁷ 17% in plastic surgery journals shows that reporting sample size is an area of

Table 1: STROBE statement adherence of all the articles (n=271)

	Item no.	Recommendation	Yes %	Partly %	No %
Title and abstract	1	(a)	19	24	56
		(b)	98	0	1
Introduction	2	Background / rationale	86	12	2
		3	Objectives	93	4
Methods	4	Study design	50	22	28
		5	Setting	83	9
Participants	6	(a)	92	6	3
		(b) n=60 Case Control Cohort	32	5	63
	7	Variables	69	13	19
		8	Data sources/ measurement	83	7
	9	Bias	12	1	87
		10	Study size	34	5
	11	Quantitative variables	70	4	26
		12	(a)	54	4
(b)	13		0	87	
(c)	1		0	99	
(d)	1		0	99	
(e)	1		0	99	
Results		Yes	Partially	No	
Participants	13	(a)	82	11	7
		(b)	14	0	86
		(c)	6	0	94
Descriptive data	14	(a)	85	11	4
		(b)	11	0	89
		(c) Cohort study (n=40)	28	0	73
Outcome data	15		88	4	8
Main results	16	(a)	53	4	43
		(b)	28	2	70
		(c)	4	0	96
Discussion	17	Other analyses	32	4	64
		18	Key results	95	3
19	Limitations		40	2	58
20	Interpretation		87	11	2
21	Generalisability		64	14	43
Other information	22	Funding	57	0	43

concern.¹¹

Another area where there was poor reporting was in the statistics section, whereby most articles (52%) mention the type of statistical test to be used, they fail to mention how the missing data (1%) and loss to follow up (1%) was addressed in cohort and case control studies. In the present study, 95% of the articles deliberate the key results and 87% interpret them in the discussion section. 64% of the articles discussed the generalizability of the findings of the study. Only about 40% of the articles mentioned the

limitations of their study. Although, there is a fear of rejection in authors if limitations are discussed, explaining limitations helps in a great way to prevent misunderstanding and helps in future to plan a better study.¹³

It is found that across the studies done checking the compliance to STROBE checklist, some of the items had low reporting percentages consistently like bias, sample size calculation, flow diagrams, addressing the missing data and limitations, while some had consistently high reportage

Table 2: STROBE statement adherence of articles according to type of study design

	Item no.	Recommendation	Cross Sectional (%) n=211		Cohort (%) n=40		Case Control (%) n=20	
			Yes	Partly	Yes	Partly	Yes	Partly
Title and abstract	1	(a)	17	24	22	22	35	35
		(b)	97	0.5	100	0	100	0
Introduction	2	Background/ rationale	85	14	87	10	85	0
		3	Objectives	92	4	95	5	95
Methods	4	Study design	51	24	50	5	45	35
		5	Setting	85	7	80	15	75
Participants	6	(a)	97	2	72	17	75	20
		(b)	NA	NA	37	0	20	15
	7	Variables	69	11	70	15	60	25
		8	Data sources/ measurement	86	6	70	12	80
	9	Bias	9	1	22	0	15	0
		10	Study size	35	6	32	2	25
	11	Quantitative variables	70	4	67	5	70	5
		12	(a)	55	3	52	10	40
(b)	11		0	25	0	5	0	
(c)	1		0	2	0	5	0	
(d)	1		0	0	0	0	0	
(e)	1		0	2	0	0	0	
Results		Yes	Partly	Yes	Partly	Yes	Partly	
Participants	13	(a)	84	11	80	10	60	20
		(b)	12	0	27	0	5	0
		(c)	4	0	10	0	15	0
Descriptive data	14	(a)	91	5	72	22	40	55
		(b)	11	0	15	0	5	0
		(c)	0	0	27	0	15	0
Outcome data	15		92	2	77	7	65	10
Main results	16	(a)	56	3	50	7	25	5
		(b)	28	1	25	2	30	5
		(c)	0	0	25	2	5	0
Discussion	17	Other analyses	31	4	37	5	20	10
		18	Key results	97	2	90	7	85
19	Limitations		36	2	52	0	60	0
20	Interpretation		86	13	87	10	90	0
21	Generalisability		67	15	50	12	60	5
Other information	22	Funding	57	0	55	0	65	0

In the present study items which had more than 70% compliance across the studies were abstract, background and rationale, the study objectives, the inclusion criteria, participants. Plausible explanation for this may be due a fact only a very few journals have endorsed STROBE as a requirement of article submission for the authors. Journals like PLOS One has published a strong endorsement for STROBE checklist in their editorials.¹⁴ However, a study found that this kind of endorsement led to a little change in reporting observational studies.⁶ Items

like finance and declaring the conflict of interest remains in the purview of the editorial decisions of the respective journals. In the present study 57% mentioned about the funding sources. No articles declared the funding source in the 35 articles studied describing hand surgery.¹²

A study by Garin et al¹⁵ in the dermatology journals published between 2004 and 2010, found an overall improvement in reporting the observational studies which was not attributed to STROBE checklist. A systematic review by Rao et al¹⁶ in journals publishing articles related to CKD, concluded that only four items (objectives reporting, choice of quantitative groups and description of and carrying out sensitivity analysis) out of the 22 items of the STROBE had some improvement after STROBE statement. A systematic review by Stevens et al¹⁷, on relation to the journals endorsement of reporting guidelines to completeness of reporting led to the finding that the completeness did not change despite the journals' endorsement of guidelines. A Randomized Control Trial by Cobo et al¹⁸ on the quality of manuscripts reviewed using reporting guidelines including STROBE found that adhering to the reporting guidelines improved the final quality of the manuscript, however they failed to demonstrate it conclusively. They also concluded that the authors follow conventional reviews than adhering to the guidelines, which probably indicates difficulties faced by

the authors in following the reporting guidelines.

The study had few limitations. The journals selected for evaluation were not specific to any specialty, and many specialty journals were not included. The timeline for selection of the articles was arbitrarily fixed from 2011 to 2015.

Conclusion

The overall reporting of articles according to STROBE was suboptimal. Items such as bias, flow diagram, missing data, subgroup analysis, mentioning the type of article in the title, had less than 30% adherence, some of the items such as abstract, background, rationale, key results, interpretation of results, objectives and study settings had a good 70% of articles adhering to them. The completeness of reporting did not differ in the three types of observational study designs.

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