* Title: Assessment of methodological description and ethical aspect in research articles published in medical journals: A critical appraisal
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Assessment of methodological description and ethical aspect in research articles published in medical journals: A critical appraisal

**Abstract**

A research article is often judged by the methodological details provided in it. Insufficient methodological information is one of many the reasons of manuscript rejection. A critical appraisal of 239 medical research articles published in three different medical journals was undertaken to assess the reporting of methodological description and ethical aspects of the published research articles. The tool for assessment of the articles included criteria like reporting of eligibility criteria, exclusion criteria, sample size, consent of the study participant, approval from Institutional ethics committee etc. In the present study it was found that exclusion criteria were lacking in 32.82% of the articles while 80% articles of clinical trials lacked data of sample size. While assessing reporting ethical aspects of research, it came to light that 29.71% articles failed to report details of ethical clearance from institutional ethics committee.

**Introduction**

Doing research is only half of the picture. Publication is the last and important stage of any research work. The roots of scholarly scientific publishing can be traced to 1665, when Henry Oldenburg of the British Royal Society established the *Philosophical Transactions of the Royal Society*. The aim was to create a public record of original contributions and to encourage scientists to “speak” directly to one another. An author's obligation is not only to release data and materialsto enable others to verify or replicate published findings (as journals already implicitly or explicitly require), but also to provide them in a form on which other scientists can build with further research. (1) All parts of an article, specifically the abstract, material and methods, results, discussion and references sections should contain certain features that should always be considered before sending a manuscript to a journal for publication. (2) However, a research article is often judged by the methodological details provided and articles with insufficient methodological information are considered less reliable. Though it is considered to be one of the easiest part to write, often manuscripts are rejected because there is insufficient detail in the methods section. Hence, the present study was undertaken to assess the methodological quality in medical research articles.

**Aims & objectives**

* To evaluate the methodological quality of research articles
* To evaluate the ethical practices of the research articles

**Materials and methods:**

This survey was done in the Department of Pharmacology of P.D.U. medical college. Three open access online journals, indexed in Copernicus and Scopus, were selected randomly. All the research articles that satisfied inclusion and exclusion criteria were downloaded from the internet.

Inclusion criteria:

* Original research articles published in the selected journals in January- December,2015

Exclusion criteria:

* Review articles
* Meta-analysis
* Cost analysis
* Questionnaire based survey
* Analytical surveys
* In vitro experiments
* Preclinical studies
* Case reports

Of the total 442 articles, based on inclusion criteria 239 articles were selected. Out of 239, 155 articles were of observational studies and the rest were of randomized controlled trial. Material and method part of all the selected articles were read thoroughly. To scrutinize methodology of observational studies, 9 criteria namely study design, eligibility criteria for study population, exclusion criteria, sample size, site and duration of the study, procedure of data collection, materials used in the study and method of statistical analysis were used. These criteria were derived from STROBE statement. For 84 articles of randomized controlled trial, two additional criteria such as method of randomization and method of blinding were evaluated which were selected from CONSORT statement. For evaluation of ethical aspect of the research articles, ethical clearance from IEC and informed consent of the study participants were used. Each criterion was specifically defined and evaluated as 0 or 1 or 2. (0=lack of documentation of criterion in the article, 1= criterion has been specified as per defined and 2=not applicable)

Data analysis was done using Microsoft Excel.

**RESULT**

In the present study, total 239 articles published in three different journals were assessed to evaluate methodological quality and ethical issues.

1. Distribution of articles:

Out of all the articles, 152 were of observational type of studies while 87 were clinical trials.

Chart 1: Distribution of articles

1. Assessment of articles:

Table 1 shows the number of articles in which the defined criteria were specified. Details regarding “study population” was specified in maximum number of articles which is 94.14%., while “method of statistical analysis” was the most neglected criteria. It was specified in only 52.72% of articles.

Table 1: Assessments of articles:

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| --- | --- |
| **Criteria to be assessed** | **No. of articles (out of 239) fulfilling individual criteria** |
| Study design | 173(72%) |
| Eligibility criteria for study population | 225(94.14%) |
| Exclusion criteria | 161(67.36%) |
| Sample size | 202(84.51%) |
| Study duration | 171(71.54%) |
| Site | 203(84.91%) |
| Ethical clearance | 168(70.29%) |
| Consent of the study participants | 164(68.61%) |
| Data collection procedure | 205(85.77%) |
| Method of statistical analysis | 126(52.72%) |
| Material used | 216(90.37%) |

1. Assessment of clinical trials:

Out of total 239 articles, 87 articles were of clinical trials. Assessment of two additional criteria such as method of randomization and method of blinding was done. Method of randomization was described in only 8% of the articles. Out of 87 clinical trials, 79 trials were blinded (single or double blinded) in which method of blinding was mentioned only in 22.78% of the articles.

1. Observational studies Vs. Clinical trials:

Comparison between articles of observational studies and clinical trials is graphically demonstrated in chart 2. Chart shows that the documentation in these articles is quite different. The major difference was seen in documentation of sample size and duration of the study. In observational studies, documentation of sample size and duration of the study was done in 82.89% and 74.34% of articles respectively, while in clinical trials it was done in 20.48% and 11.69% of articles respectively.

Chart 2: Comparison of findings of articles of observational studies and clinical trials

DISCUSSION:

Critical appraisal is a systematic process used to identify the strengths and weaknesses of a research article in order to assess the usefulness and validity of research findings. (3) Asking questions about an article’s research methodology, scrutinizing its data collection and analysis methods, and evaluating how its findings are presented will help you to determine whether that article’s conclusions should influence practical decision-making.(4) A careful assessment of the key methodological features of a study design is one of the important component of critical appraisal.

According to Sackett, about two thirds of 56 typical errors in studies are connected to errors in design and performance in which study design included type of study, study population and sample size. (5) Choosing an appropriate design is a critical step. Study type and design, if provided in an article guides other scientists to choose proper design while conducting research and avoid errors, while choosing an appropriate sample size gives a study adequate power to detect the significance difference. In the present study, out of 239 articles, type of the study and sample size were described in 72% and 84.51% of the articles respectively. However, when data of observational studies and clinical trials was compared, we found that 80% articles of clinical trials lacked data of sample size.

According to G.T. Clark, R. Mulligan (2011), a common omission from many research papers is the lack of inclusion and exclusion criteria.(6) Listing these criteria helps other researchers understand why current results might differ from other published studies. In our study, exclusion criteria were lacking in 32.82% of the articles.

Autonomy, beneficence, non-maleficence and justice are the basic rights of the human participants of any research projects. Human participation should only be followed by informed written consent of the participant/guardian of the participant. The institutional ethics committee (IEC) is responsible for preservation of these rights. Thus, no research project should be conducted without the permission of IEC and details of approval should be documented in the article published. An assessment of ethical consideration of journal articles was done by Belhekar M, Bhalerao S and Munshi – Kulkarni R and they found that out of 311 articles published in 4 different journals, 58.2% articles lacked ethical practice reporting. (7) In our study, 29.71% articles failed to report details of ethical clearance while detail of consent of the subjects was lacking in 41.39% articles.

In Randomized controlled trials, the random allocation of participants should ensure that treatment groups are equivalent in terms of both known and unknown confounding factors. Randomization and blinding allows to avoid bias. In our study, 92% of the articles failed to specify method of randomization and 77.22% of the articles failed to specify method of blinding.

Thus, in the present study, it was found that reporting of research methodology in the articles published in medical journals is insufficient. Material and methods section is the core of any medical research article. This section is usually very straightforward, and it helps many people establish the proper thought process and understanding of the work. As it is considered to be one of the easiest part to write, researchers and writers should be stressed upon writing this section carefully and responsibly.

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