

Reporting of adverse drug reactions in clinical trials published in Indian Medical/Dental journals

Every year, a large number of clinical trials studying pharmacological agents are published in the Indian medical/dental Literature. Data on potential adverse drug reactions (ADRs) occurring during such studies needs to be presented in a standardized manner that is reproducible and facilitates an accurate comparison among these studies to form an informed decision on a particular pharmacological agent. The CONSORT (Consolidated Standards of Reporting Trials) group has emphasized on this important aspect of clinical studies by providing a separate supplementary checklist CONSORT “Checklist for Harm” for reporting detailed information on adverse drug reactions.^[1] There is paucity of data on ADRs from clinical trials published in Indian Medical/ Dental journals. Thus, we reviewed the practice of ADRs reporting in clinical trials published in Indian medical/ dental journals in the last four years and critically evaluated them for deficiencies in reporting practices.

To identify clinical trials published in Indian medical/dental journals for our study, we searched PubMed indexed journals using a variety of search strategies using unique MeSH terms such as “Clinical Trials [Publication Type]”, “Pharmaceutical Preparations,” and restricted our search results to Indian medical/dental journals. Criteria for inclusion included a clinical trial involving study of at least one pharmacological agent published in Indian medical/dental journals and published in the last four years (2007–2011). All observational studies, post marketing surveillance studies, studies published in non-Indian journals were excluded. Our search strategy retrieved 46 titles matching our inclusion criteria published in 17 different Indian medical/dental Journals. Each study was independently reviewed on basis of a pre-specified checklist by the first and second author (PM, TB) and conflicts were resolved with mutual consensus.

Based on the methodology adopted by Loke *et al*, we evaluated each article on the following criteria.^[2]

Reporting of specific clinical events as possible ADRs was defined as a mention of specific clinical events e.g. respiratory depression and edema which could potentially be causally related to the pharmacological agent under study.

Generic statements such as “Monitoring for adverse effect was undertaken” were deemed insufficient in fulfilling this criterion.

Studies were evaluated for sufficient description of the different methods i.e. patient reported, active physician surveillance or by the use of specific diagnostic tests adopted by the study investigators to proactively identify potential ADRs.

Reporting of severity of ADRs was deemed to be fulfilled when use of precisely defined severity tools such as Acne Severity Index (ASI) was used to grade the severity of the ADRs.

Studies were evaluated for presentation of numerical data on ADRs such as headache (17%), depression (3%) in either a tabular form or within the text.

Descriptive statistics in the form of frequency, percentage as well the 95% confidence interval was used to describe our findings. Analysis of the data was done using Epi Info™ Version 3.5.1

We were unable to retrieve full-length papers on six of the 46 titles though they were cited on PubMed. The frequencies (percentage) of reporting of various endpoints have been summarized in Table 1. Out of the 40 articles, nineteen (47.5%, 95% CI 32.9–62.5%) articles provided information about clinical events that could causally be linked to pharmacologic intervention used in the study. Twenty six (65%, 95% CI 48.3–79.4%) articles discussed information on at least one method of monitoring that was adopted for monitoring adverse drug reactions. Five (12.5%, 95 % CI 73.2 – 95.8%) articles employed a clearly defined grading scale to present the severity of ADRs and only 13(32.5%, 95% CI 18.6 – 49.1%) presented precise numerical data regarding the incidence of ADRs occurring during the trial.

Table 1: Description of the summary statistics

Checklist criterion	Number of studies reporting data (n= 40)	(%)
Reporting of specific clinical events as possible ADR	19	47.5
Sufficient detail regarding at least one method of monitoring for adverse drug reaction	26	65
Patient reported	13	32.5
Physician monitoring	25	62.5
Use of diagnostic/Laboratory tests	5	12.5
Reporting of severity of ADR	5	23.5
Numerical reporting of data on ADR	13	32.5

Almost 88% of the clinical trials published in the western journals mention minimal information on ADRs.^[3] In contrast, our study revealed that almost a third of the clinical trials published in the Indian literature make no attempt to mention even basic minimal information on ADRs. This leaves much room for improvement in reporting of data on ADRs. While we understand the space and word constraints in submitting a manuscript, the practice of mentioning the bare essential information in a standardized manner can tremendously improve the validity of the study. Additionally, with increasing amount of journals adopting the online platform, detailed information about potential adverse effects during the study can be provided in the form of a supplementary index. Our study is limited by the small sample size and assessment of only Pubmed indexed journals. Nevertheless, our study provides a useful snapshot of the current scenario of reporting of adverse effect in the Indian literature and the scope of improvement present and a platform for an effort to improve reporting of data on adverse reactions published in Indian journals.

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