



Chapter 9

CRITICAL EVALUATION OF BIOMEDICAL LITERATURE

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INTRODUCTION

- Reviewing the 'Biomedical Literature' poses a great challenge to the clinical professionals.
- evaluating a scientific article is a complex task.
- Knowledge of the standard anatomy of an article and idiosyncrasy of various types of studies will assist the reader to review the 'Biomedical Literature' efficiently.

Biomedical research

- It is the basic research, applied research or translational researches conducted to aid and support the body of knowledge in the field of Clinical Practice.

Literature evaluation

- It is the process of reading and evaluating article, journal, literature, and scientific study in a systematic way to reach at a conclusion that one can interpret itself whether the study results are scientifically proved and applicable to Clinical Practice.

Scientific Study

- It is a written and published report that describes original research results. Scientific studies are written in a style that is exceedingly clear and concise. A well-written scientific literature explains the author's interest. Author should summarize and give an idea on previous research, and Reader should be able to distinguish between previous research and the actual current study

Critical Appraisal

- It is the process of systematically examining research evidence to assess its validity, results, and relevance”.
- Critical Appraisal is a way to assess the scientific value and trustworthiness of a study published in a research article. It helps people in developing necessary skills to make true judgments of a scientific literature

Selecting the Article

- Primary step in evaluation of a literature is to select an article which has a greater impact in clinical practice. Initially, read the title, authors and abstract. The title should be comprehensive that the reader can efficiently analyze the article's potential and its importance in current clinical practice. If not, reader can reject it and move on to the next article.

Reading the Literature

- Reviewing begins with reading and understanding the abstract or short summary that gives a brief background about the research. Initial reading gives the concept of objectives, methodology, results and proposed significance of the study. A proper understanding of research study's nature is must for a reader.



Biomedical Literature includes critical appraisal of the following contents:

Title

- ‘Title’ describes the breadth and depth of the current study and indicates the methodology used. It is the limited possible words that adequately describe contents of the study. The title of an article should be brief, definite and concise and should catch the attention of the readers interested in the study

Evaluation of Title

1) Based on the title itself reader cannot review or discard the study.

2) Title should not contain abbreviations, proprietary names, chemical formulae, and jargons.

The title should inform the real subject of the article.

3) Title should not reflect its content. First impression is the best impression; the title should be specific and studied well.

4) Title should not indicate author's preference for any specific subject

Abstract

- an abbreviated accurate representing the contents of a document, mainly prepared by its author(s) for publication in it.
- abstract can be defined as a summary of the information in a document.
- A synopsis (not more than 250 words) should be mentioned before introduction in the article.

Evaluation of Abstract

- 'Abstract' should outline a brief
- summary of each section; Introduction, objectives, scope of investigation, materials and brief
- methodology, results, and conclusion which indicates study findings. Abstract does not provide
- complete information about the study and should not be used alone to evaluate the study

Introduction

- It serves two purposes in the study, creating readers interest in subject and providing them with enough information to understand the study.

Evaluation of Introduction

- Introduction should be presented, with all possible clarity, the nature and scope of the problem investigated.
- It should provide pertinent literature to orient the reader.
- It should explain the reason why the current research is needed?

Objective

- ‘Objective’ of a study is what the author is trying to achieve. It is a specific, clear and succinct statement of intended outcomes from research. Objective should be stated in a clear and concise manner.

Evaluation of Objective

1. Establishing new health programs
2. Implementing new policies
3. Trying to settle a controversy
4. Showing the validity of a new technique
5. Opening up a new field of inquiry.

Materials and Methods

- Methodology is one of the most important sections of a study. Its purpose is to describe the methods used in the experiment and materials by which the experiment was carried out. The description of this section should be detailed enough to allow other researchers to replicate the work.

Evaluation of Study Methods

- Methods used, and their description should be elucidated.
- What are the dose regimens, route and frequency of administration, the overall length of the study to be mentioned.
- What was the length of wash-out period

Study Designs

- The first part of this section is generally an overview of the type of study design that is utilized in doing research. A sound study design supports study conclusion and result. Study design should be clear and provide enough details so that potential reader can repeat the research

Various types of Study design

- **Observational studies**

Data collected from one or more group of subjects, Observational studies may be prospective or retrospective.

- **Single blind**

Either subjects or investigators are unaware of treatment allocation.

- **Double blind**

Neither subjects nor investigators are aware of treatment allocation.

- **Triple blind**

Subjects and investigators are unaware of treatment allocation; another group involved with interpretation of data is also unaware of treatment allocation.

- **Parallel study**

All subjects receive only one treatment.



- **Prospective**

Data is collected forward in time from the start of the study.

- **Retrospective**

Historical data (i.e., data referring to past events) is collected.

- **Cohort studies**

Cohort studies consist of prospective observation of one or more groups with certain characteristics.

- **Randomized control trial**

Subjects are randomly allocated to either an intervention group or control group. Randomized controlled trials are described as the “gold standard” in clinical research.

Evaluation of Study Designs

- The study design selected by an investigator should be sound and likely to answer the research questions.
- Author(s) must describe study population well enough so that the reader is able to visualize the sample population precisely under investigation.

Bias

- It is a systemic variation in which treatment groups under study are treated or measured differently on a consistent basis. Bias can mislead one to get into an erroneous outcome. The reader should be able to find out the source of bias and its influence on the final outcome of study

Types of bias

- **Missing clinical data bias**

Certain clinical data may be missing because they were normal, negative or never measured.

- **Withdrawal bias**

Patients who withdraw from a study may differ from those who remain.

- **Sample size bias**

Too small Samples are insignificant; samples which are too large are proved to be helpful.

- **Instrument bias**

Defects in the calibration or maintenance of instruments may lead to systematic deviations in results.

Statistics

- Knowledge of 'Statistics' can help an individual to evaluate whether the statistical tests used in a study are appropriate or not. Different types of data (or variables) are encountered in statistics. Errors in statistical analysis of data lead to invalid result/conclusion

TYPES OF DATA	TWO COMPARISON GROUPS	MORE THAN TWO COMPARISON GROUPS	
	UNPAIRED DATA	PAIRED DATA	UNPAIRED DATA
Nominal	Chi square	McNemar	Chi square
Ordinal	Mann-Witney U test	Wilcoxon	Kruskal-Wallis
Parametric	Student t-test	Paired student test	Analysis-of variance (ANOVA)

Evaluation of Statistics

- Readers should determine whether appropriate statistical methods were used for data analysis.
- Use of inappropriate methods will result in misleading conclusions.
- Method section of any scientific literature should include a summary description of the statistical tests that were used to evaluate data. Qualitative and quantitative data are examined differently.

Study Results and Analysis

- ‘Results’ should be described and presented in figures, tables, and charts, as they are the heart of the scientific literature.
- Figures, tables, and charts will assist the reader in deciding whether it is worth to read the rest of the article or to discard it.
- A properly conducted study should present data on subjects involved in the study. All the data collected in the method section should also be presented

Evaluation of Study Results and Analysis

- reader should have a proper understanding of study and should evaluate clinical and statistical reliability of the study
- Sometimes authors try to present results in a confusing way, which most likely reflects hap hazardous data collection and lack of clearly defined study objectives.
- Are the negative results been quoted? In case of any negative results those should be quoted and the limitations have to be specified.

Discussion and Conclusion

- ‘Discussion Section’ of a study provides an opportunity for the author to interpret results and explain their clinical importance by relating or comparing with previous work or practice.
- ‘Conclusion’ is the author’s generated inferences, opinions and hypotheses about results. This section should contain views that the author draws from data obtained by the study

Evaluation of Discussion and Conclusion

- Is the conclusion over-generalized? The 'Conclusion' must be clear and understandable to the reader. Conclusion must be consistent with study objectives and justified by results.
- Conclusion should not be a matter of dispute.
- How does the research fit into the context of its conclusion? It should give the answer of the study objective for which claim was made prior to study.
- Readers must understand the relationship between the data and the conclusions.

References

- While writing article, authors always refer to some information from other sources.
- All these sources are listed in 'Reference Section', sometimes referred to as 'Bibliography'.

Evaluation of References

- 1) Are the references given? Whether appropriate and adequate references are used in the study?
- 2) Are the references quoted appropriately in the research article?
- 3) Are the references given recent and important?
- 4) What is the size of 'Reference Section'?
- 5) How the references are used for support, rebuttal etc.?
- 6) Do the references match citations in the text?
- 7) Authors should avoid citing their own research efforts and publication.