

Critical appraisal of published literature

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ABSTRACT

With a large output of medical literature coming out every year, it is impossible for readers to read every article. Critical appraisal of scientific literature is an important skill to be mastered not only by academic medical professionals but also by those involved in clinical practice. Before incorporating changes into the management of their patients, a thorough evaluation of the current or published literature is an important step in clinical practice. It is necessary for assessing the published literature for its scientific validity and generalizability to the specific patient community and reader's work environment. Simple steps have been provided by Consolidated Standard for Reporting Trial statements, Scottish Intercollegiate Guidelines Network and several other resources which if implemented may help the reader to avoid reading flawed literature and prevent the incorporation of biased or untrustworthy information into our practice.

Key words: Allocation concealment, bias, conflict of interest, critical appraisal, randomisation, study design

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INTRODUCTION

Critical appraisal

'The process of carefully and systematically examining research to judge its trustworthiness, and its value and relevance in a particular context'

-Burls A^[1]

The objective of medical literature is to provide unbiased, accurate medical information, backed by robust scientific evidence that could aid and enhance patient care. With the ever increasing load of scientific literature (more than 12,000 new articles added every week to the MEDLINE database),^[2] keeping abreast of the current literature can be arduous. Critical appraisal of literature may help distinguish between useful and flawed studies. Although substantial resources of peer-reviewed literature are available, flawed studies may abound in unreliable sources. Flawed studies if used to guide clinical decisions may end up with no benefit or at worse result in significant harm. Readers can, thus, make informed decisions by critically evaluating medical literature.

STEPS TO CRITICALLY EVALUATE AN ARTICLE

Initial evaluation of an article published in literature should be based on certain core questions. These

may include querying what could be the key learning points in the article, about its clinical relevance, if the study has a robust methodology, if the results are reproducible and could there be any bias or conflict of interest [Table 1]. If there are serious doubts regarding any of these steps, the reader could skip the article at this stage itself.

Introduction, methods, results and discussion pattern of scientific literature

Introduction

Evaluate if the need (as dearth of studies on the topic in scientific literature) and the purpose of the study (attempting to find answers to one of the important unanswered queries of clinical relevance) are properly explained with scientific rationale. If the research objective and hypothesis were not clearly defined or the findings of the study are different from

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the objectives (chance findings), the study outcomes become questionable.

Methods

A good working scientific hypothesis backed by a strong methodology is the stepping stone for carrying out a meaningful research. The groups to be involved and the study end points should be determined prior to starting the study. Strong methodology depends on several aspects that must be properly addressed and evaluated [Table 2]. The methodology for statistical

analysis including tests for distribution pattern of study data, level of significance and sample size calculation should be clearly defined in the methods section. Data that violate the assumption of normal distribution pattern must be analysed with non-parametric statistical tests. Inadequate sample size can lead to false-negative results or beta error (aide-memoire: beta error is blindness). Setting a higher level of significance, especially when performing multiple comparisons, can lead to false-positive results or alpha error (aide-memoire: alpha error is hallucination). A confidence interval when used in the study methodology provides information on the direction and strength of the effect, in contrast to *P* values alone, from which the magnitude, direction or comparison of relative risk between groups cannot be inferred. *P* value simply accepts or rejects the null hypothesis, therefore it must be reported in conjunction with confidence intervals.^[6] An important guideline for evaluating and reporting randomised controlled trials, mandatory for publication in several international medical journals, is the Consolidated Standard for Reporting Trial (CONSORT) statement.^[7] Other scientific societies such as the Scottish Intercollegiate

Table 1: Core questions for initial evaluation of a scientific article

Question number	Core questions for initial evaluation
1	Does the study have a scientifically interesting and important aim?
2	Will the study outcome provide a clinical significance to the reader?
3	Is the methodology well designed?
4	Is the primary outcome variable properly evaluated?
5	Is the sample size large enough to find a reliable and meaningful difference or effect?
6	Is there a significant reason to doubt the validity of the findings (poor methodology, insufficient sample size and large confounders)?

Table 2: Appraisal elements for robust evaluation of study methodology

Appraisal item	Evaluation to be done
Registration, ethics and funding	Written informed consent from participating patients and for any images of patients to be displayed/published. Source of funding as disclosed. Approval from relevant sources depending upon the nature and design of the study and registration into a clinical trials registry
Design	Note description of trial design, if it has been identified as a randomised trial in the title and abstract
Methodology	Patient selection, interventions, randomisation, blinding, clearly defined primary and secondary outcome measures and tools used for the assessment of the outcome variables. Clarity on how often these variables were assessed, by whom and how often were the study population followed up
Similarity	The same conditions should be applicable to both control as well as the study groups except for the study intervention. Bias usually tends to favour the study group; hence, any deviation from the methodology other than the intervention automatically becomes a bias ^[3]
Randomisation	Eliminates bias to assess the effect of chance, note if generated by computer or by lots, if block randomisation was done
Allocation concealment, masking or blinding	Ensure all the study investigators were unaware of the patient allocation to groups and did not exert any control over the order of randomisation of patients in the trial. ^[4] This is essential to prevent intentional or subconscious (prejudiced) allocation
Sample size estimation and statistics	Details of how the authors determined sample size for the study by a <i>priori</i> analysis or pilot study. Power of the study was $\geq 80\%$ and the confidence interval ($\geq 95\%$) was appropriate. Effect size used to detect difference in the primary outcome variable deemed clinically relevant. <i>Post hoc</i> analysis is usually unacceptable. Any violation of the assumption of normal data distribution. Use of appropriate statistical test
Participant flow	Evaluate the flow chart (CONSORT flow diagram) if all patients were accounted for in the study. If there were any dropouts, the article should provide description of reasons for the dropout
Reliability	Investigators provided information that they have made an honest effort to minimise random error (chance errors). Assess involvement of unstable patients that result in the values or assessments to differ at different points making the results less reliable or questionable ^[5]
Results analysis	Baseline demographic, clinical data, results of outcomes in each study group, results of subgroup analysis
Generalizability	The scoring systems, protocols used, equipment or instruments used for the measurement of outcome variables are available at the workplace of the appraiser. Any deviation or use of different, albeit similar measurement system might alter the outcome ^[5]
Limitations, interpretation	Sources of trial limitations and if interpretation is consistent with results

CONSORT – Consolidated Standard for Reporting Trial

Guidelines Network have devised checklists that may aid in the critical evaluation of articles depending on the type of study methodology.^[8,9]

Results

The results section should only report the findings of the study, without attempting to reason them out. The total number of participants with the number of those excluded, dropped out or withdrawn from the study should be analysed. Failure to do so may lead to underestimation or overestimation of results.^[10] A summary flowchart containing enrolment data could be created as per the CONSORT statement.^[5] Actual values including the mean with standard deviation/error or median with interquartile range should be reported. Evaluate for completeness – all the variables in the study methodology should be analysed using appropriate statistical tests. Ensure that findings stated in the results are the same in other areas of the article – abstract, tables and figures. Appropriate tables and graphs should be used to provide the results of the study. Assess if the results of the study can be generalised and are useful to our workplace or patient population.

Although significant positive results from the study are more likely to be accepted for publication (publication bias), remember that high rates of falsely inflated results are demonstrated in studies that had flawed methodology (due to improper or lack of appropriate randomisation, allocation concealment, blinding and/or assessing outcomes through statistical modeling). Further, the publication bias towards studies with positive outcome leads to scientific distortions in the body of scientific knowledge.^[11,12]

Discussion and conclusion

The discussion is used to account for or reason out the outcomes of the study, including dropouts and any change in methodology, to comment on the external validity of the study and to discuss its limitations. The authors should report their findings in comparison with that previously published in literature, if the study results added new information to the current literature, if it could alter patient management and if the findings need larger studies for further evaluation or confirmation. When concluding, the interpretation should be consistent with the actual findings. Evaluate if the questions in the study hypothesis were adequately addressed and if the conclusions were justified by the actual data. Authors should also provide limitations of their study and constructive suggestions for future research.

Readers may find useful resources on how to constructively read the published literature at the following resources:

- Consolidated Standard for Reporting Trial 2010 for randomised trials - <http://www.consort-statement.org>
- Sign checklists - <http://www.sign.ac.uk/methodology/checklists.html>
- BMJ series of articles - <http://www.bmj.com/about-bmj/resources-readers/publications/how-read-paper>
- Equator network for health research - <http://www.equator-network.org>
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- Care for case reports - <http://www.care-statement.org>
- PRISMA statement for meta-analytical studies and systematic reviews: <http://www.prisma-statement.org>
- Agree - <http://www.agreetrust.org>
- CASP - <http://www.casp-uk.net>
- <http://www.delfini.org>

SUMMARY

Critical appraisal of scientific literature is an important skill to be mastered not just by academic medical professionals but also by those involved in clinical practice. Before incorporating changes in the management of their patients, a thorough evaluation of the current or published literature is a necessary step in practicing evidence-based medicine.

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Conflicts of interest

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