

A Critical Appraisal on the “Level-of-evidence” Classification Systems

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Evidence-based medicine is about analyzing the evidence and then utilizing the same analysis in making clinical decisions. The key element of evidence-based medicine is the hierarchical system of categorizing evidence. This hierarchy is known as the “levels of evidence”.¹ Clinicians use this classification to identify the highest level of evidence to answer clinical questions. Various types of research studies answer the different kinds of clinical questions.¹

In 1979, the Canadian Task Force on Periodic Health Examination reported the levels of evidence for the first time.¹ Since the establishment of the classification of the levels, many journals and organizations have modified the classification system according to their needs. The Centre for Evidence-based Medicine (CEBM) based at the Nuffield Department of Primary Care Health Sciences, the University of Oxford has developed and modified the classification of levels. This CEBM system is recognized universally to identify the level of evidence in medical literature.² Level 1 is the highest level of evidence and level 5 the lowest. These levels categorize studies according to the chances of bias.¹ Systematic review of randomized control trials are placed at the highest level owing to their unbiased study design. Case series and expert opinions (bias of author’s views) are ranked the lowest.

Today, many classification systems are available in the literature such as levels of evidence from Sackett on the use of antithrombotic agents,³ levels of evidence developed by the American Society of Plastic Surgeons for prognostic studies, and levels of evidence developed by CEBM for treatment (therapeutic studies). These systems are used in studies related to systematic reviews, meta-analysis, and bibliometric analysis. A level-of-evidence analysis is of paramount importance in such study designs, which increases the credibility of the outcome obtained in the articles.

After a careful analysis of the available classification systems, it is observed that they are related to clinical studies. Hence, the level-of-evidence scales is not useful for the following scenarios:

SYSTEMATIC REVIEWS, META-ANALYSIS, OR BIBLIOMETRIC ANALYSIS THAT ARE NOT RELATED TO TREATMENTS

Such research papers include studies on histopathology, demographic analysis, epidemiological studies, and biochemical investigations. Even though such studies are directly or indirectly associated with the patients, it is not possible to determine the level of evidence in such studies.

FORENSIC SCIENCES

Usually studies in such cases involve victim identification, sex determination, age estimation, bite mark analysis, finger print analysis, etc. It is not possible to use the existing level-of-evidence classifications.

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IN VITRO STUDIES

Studies that involve the testing of material strengths of implants, restorations, prosthesis etc. is not eligible for the level-of-evidence analysis.

LABORATORY PRECLINICAL STUDIES

These are based on the cell-lines-related experimentations. Such studies cannot come under the purview of the level-of-evidence analysis.

ANIMAL STUDIES

Although drug trials on animals are considered as clinical studies, currently there are no level-of-evidence scales designed for such studies.

Looking at these aspects, it is the need of hour to design, develop, and validate appropriate classification systems for measuring the level of evidence for the aforementioned scenarios. Such kinds of scales will definitely improve the credibility and standard of the outcomes obtained through systematic reviews, meta-analysis, or bibliometric analysis on non-clinical studies.

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