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Letter to Editor

Recognizing the vital role of low-level evidence in medical research

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Dear Editor,

In the era of Evidence-Based Medicine (EBM), scientific testimonials are the cornerstone upon which, theories are formulated, policies are made, and knowledge advances. In the evidence pyramid, high-quality randomized controlled trials (RCTs) have been established as the gold standard for primary data sources.[1] Evidence from the base of the pyramid is considered low-rated.[2] These include expert opinion, editorials, case reports, animal and in-vitro studies, or test tube studies. These studies often lack transparency, reproducibility, and statistical power. There might be inconsistencies in the data reporting, a high risk of bias, and poor generalizability. However, it is crucial to recognize and appreciate the importance of low-level evidence in the broader spectrum of scientific evidence. Moreover, low-level evidence may also augment the evidence base by complementing higher-level research methodologies. While these forms of evidence may lack the rigor and statistical power associated with RCTs, they offer unique contributions that enrich the research process in several ways.

First and foremost, low-level evidence is a helpful starting point for formulating hypotheses and pursuing new areas of investigation. Case reports, for example, contain extensive descriptions of some atypical or unique clinical presentations. They provide real-world scenarios with tailored management approaches according to available resources and facilities. This widens insight into potential disease processes and/or treatment approaches. These observations can refine further research questions and guide the design of more robust studies accordingly. In sectors, where performing RCTs may be impractical or unethical, such as in uncommon diseases or developing medical therapies, observational studies, and case series provide vital data for interpreting treatment outcomes and evaluating safety profile.[3]

Furthermore, low-level evidence often serves as a critical source of information in areas where high-quality research is scarce or limited. In resource-constrained settings or for conditions that are under-studied, relying solely on RCTs may lead to gaps in knowledge and hinder progress in clinical practice. Low-level evidence can be utilized to address research gaps related to rare diseases and orphan drugs.[4] Embracing low-level evidence allows researchers and clinicians to leverage existing data and address some unique clinical questions, particularly in fields where large-scale trials may not be feasible due to various reasons.[5]

Observational studies without control groups form another important kind of low-level evidence. These studies help in identifying potential risk factors for diseases. The association between smoking and lung cancer was initially observed in case series and observational studies, leading to more rigorous research designs that confirmed the causal link.

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During infectious disease outbreaks, (such as Monkey pox and Ebola) low-level evidence is often the only available data that can guide public health responses. Early case reports and small studies during the COVID-19 pandemic provided crucial information on transmission, clinical presentation, and potential interventions, which were vital for formulating immediate public health actions.

Expert opinion, personal experience, editorial, and perspectives form the ground for planning scientifically sound research projects and results obtained from this research help in evidence generation. Additionally, low-level evidence may also play a vital role in enhancing the patient-centred approach of research and clinical decision-making. Case reports and patient narratives offer valuable information about diseases and treatment modalities. By incorporating patient narratives into the management of the disease process, clinicians can gain a deeper insight into the personal experience of disease and tailor interventions to meet the diverse needs of patients.[6]

Low-level evidence has certain imitations too. It is also necessary to recognize the limits of observational studies and case series in proving causality and generalizability. While they can provide significant insights, they should be read within their context, with an understanding of potential confounders. It is equally important to make a balance between leveraging existing data and advocating for the generation of higher-quality evidence where feasible. Despite its inherent limitations, low-level evidence should not be discarded or neglected in the evidence generation. Instead, it should be considered as a complementary and valuable component of the evidence base, providing unique insights and addressing critical knowledge gaps. Researchers and clinicians should approach low-level evidence with caution, critically evaluating its quality and relevance before incorporating it into decision-making processes.[7]

Low-level evidence is indispensable in biomedical research, particularly in the early stages of an outbreak and in contexts where high-level evidence is not yet available or feasible. Low-level evidence is not as reliable as high-level evidence, it still plays a crucial role in the early stages of research, particularly in hypothesis generation. While low-level evidence might give unique insights and cover specific knowledge gaps, it should be considered complementary rather than a replacement for higher-quality evidence. Researchers and clinicians should use a balanced approach to evidence synthesis and evaluation, leveraging low-level evidence where gold standard evidence is lacking while prioritizing the generation of high-quality evidence through rigorous research methodologies like RCTs. This critical examination emphasizes the need for careful interpretation and integration of evidence across diverse domains to promote innovation, improve patient outcomes, and advance scientific understanding.

1. Conflict of Interest

None.

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