

The philosophy of evidence-based clinical practice: Is evidence enough?

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A 36-year-old never-smoker woman with no medical history was admitted for gradual, progressive dyspnea on exertion. Her extensive work-up (including pulmonary function tests, connective tissue disease panel, and chest imaging) was unremarkable except for moderate pulmonary arterial hypertension. The consult team started to discuss whether or not to start the patient on a phosphodiesterase inhibitor, but I had another two questions, which were essentially the same, in mind! Were patient-important outcomes interrogated and was the most important clinical outcome investigated?

Evidence-based clinical practice (EBCP), originally referred to as evidence-based medicine, is defined as the conscientious, explicit, and judicious use of the best evidence in making decisions about the care of individual patients.^[1] EBCP also assists decision makers in implementing best healthcare practice while drawing roadmaps for the health system.^[2] The integration of EBCP in the clinical practice, including respiratory medicine, should take into consideration two fundamental principles: The hierarchy of evidence and the art of clinical decision-making.

Evidence is usually abstracted from any empirical observation. This might be in different formats and types of studies, being systematically or nonsystematically reported. However, the unsystematic ones are often limited by the small sample size and flaws in inferences affected by the illness natural history, placebo effect, clinicians' expectations, and patients' desire to please their healthcare providers.^[3]

While the hierarchy of evidence implies that the type of study determines the level of evidence, this role has exceptions. Conventionally, randomized-controlled trials (RCTs) and their systematic reviews and meta-analyses sit at the top of the hierarchy pyramid, while case reports and series are considered weakest evidence and are located at bottom of the hierarchy system. Observational studies other than case reports and series including case-control and cohort studies are considered in the middle of the pyramid. The strength of the RCTs is obtained from its powerful design that includes randomization. This assists in eliminating the bias in the choice

of treatment assignments. It is the only mean to control for unknown prognostic factors, that is, confounders. In addition, randomization, when implemented appropriately, is the best way to achieve matching of the comparison groups for their prognostic factors.^[4] However, and as it was mentioned above, this hierarchy system is not absolute. Rigorously conducted observational studies may provide more compelling evidence than poorly-conducted RCTs.

The second fundamental principle, clinical decision-making, is very important in clinical practice and is often overlooked. A healthcare professional should always keep in mind their patients' values and preferences when taking a clinical decision.^[5] Implementation of EBCP requires careful review of the patients', and possibly cultural, acceptance of the diagnostic test, and/or management intervention. Clinical expertise is always needed and, therefore, EBCP should take into account an expert opinion when dealing with different clinical scenarios. Additionally, healthcare providers should always be good judges when mixing both EBCP and clinical expertise along with taking into consideration the economic aspect of the test/intervention.

In summary, healthcare professionals should gain a mixture of necessary qualities required for the optimal patient care that include along with the in-depth background and physiological knowledge and awareness of the available diagnostic tests and therapeutic interventions, they should acquire effective search tools, critical appraisal skills, the ability to define and understand benefits along with the ability to understand patients' and cultural values and preferences.

Returning back to the clinical scenario, the treatment of the patient should be dictated based on the specific details of the corresponding study that investigated the use of phosphodiesterase inhibitors in patients with pulmonary hypertension. The investigators used sildenafil and evaluated its effects on the distance of the six-minute walking test (6MWT) as the primary end point.^[6] They also assessed the pulmonary physiology with attention to the mean pulmonary artery pressure but as a secondary outcome.

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Therefore, and in order to obtain the best outcome from the medication, the patient described above should have a 6MWT prior to receiving the intervention of interest. This is referred to as external validity of a clinical study and generalization of its results on the patients in the clinical setting. Lastly, it is favorable to focus on patient-important outcomes and not physiological endpoints that are used as surrogate for other, usually more important, outcomes.

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