

LANGUAGE OF EVIDENCE

Defining the terms of evidence-based medicine

Alan Finkelstein, MD
UPMC Shadyside Family
Medicine Residency,
Pittsburgh, Pa

FEATURE EDITOR

Goutham Rao, MD

UPMC Shadyside Family
Medicine Residency,
Pittsburgh, Pa

About levels of evidence

Evidence grading makes it easier for busy physicians to apply the results of clinical research to their practice

Levels of evidence are assigned to studies based on the quality of their design, validity, and applicability to patient care. The Agency for Health Care Quality and Research (AHRQ) has proposed that any system assigning levels of evidence should incorporate quality, quantity, and consistency of the evidence.

Leading family medicine journals have adopted a uniform grading system known as the Strength of Recommendation Taxonomy¹ (SORT), which includes these key elements and 3 levels of evidence. SORT is one among several different methods of grading levels of evidence that make use of similar principles. SORT's primary advantage is its simplicity.

The randomized controlled trial (RCT) is the most rigorous study design. According to SORT, RCTs that deal with patient-oriented outcomes and include concealment, double-blinding, intention-to-treat analysis, and complete follow-up (and meta-analyses or systematic reviews of such randomized trials) provide Level 1 evidence. Observational studies, such as cohort and case-control studies (and systematic reviews that include them), are less rigorous in their design. They are assigned a Level of Evidence of 2. Level 3 evidence, the lowest level, is assigned to consensus guidelines, expert opinion, usual practice, and so forth, or to studies that look at intermediate or disease-oriented outcomes.

How it applies to recent findings

Although the Nurses Health Study,² a large cohort trial involving nearly 88,000 women, and other observational studies (SORT LOE: 2) suggested a cardiovascular benefit from vitamin E; the Finnish Alpha-Tocopherol, Beta-Carotene Cancer Prevention study,³ a well-designed RCT (LOE: 1), proved the opposite. A recently published Italian study⁴ provided Level 3 evidence, demonstrating that vitamin E prevented an oxidation-induced reduction in coronary blood flow. Therefore, based on the highest level of evidence available, vitamin E to prevent cardiovascular disease is not recommended.

Levels of evidence can make it easier for busy physicians to apply the results of clinical research to their practice and to incorporate evidence-based medicine into patient care. ■

REFERENCES

1. Ebell MH, Siwek J, Weiss BD, Woolf SH, Susman JL, Ewigman B, Bowman M. Simplifying the language of evidence to improve patient care: Strength of recommendation taxonomy (SORT): a patient-centered approach to grading evidence in medical literature. *J Fam Pract* 2004; 53:111-120.
2. Stampfer MJ, Hennekens CH, Manson JE, et al. Vitamin E consumption and the risk of coronary disease in women. *N Engl J Med* 1993; 328:1444-1449.
3. Virtamo J, Rapola JM, Ripatti S, et al. Effect of vitamin E and beta carotene on the incidence of primary nonfatal myocardial infarction and fatal coronary heart disease. *Arch Intern Med* 1998;158:668-675.
4. Coppola A, Astarita C, Liguori E, et al. Impairment of coronary circulation by acute hyperhomocysteinaemia and reversal by antioxidant vitamins. *J Intern Med* 2004; 256:398-405.

CORRESPONDENCE

Alan Finkelstein, MD.
E-mail: finkelsteina@upmc.edu.