Editor's Note

Decision Making in Cardiology: Judgement Based on Evidence or Experience?

Key words: decision making

Recently, I read an interesting article that relates to whether decision making in cardiology is based on evidence or experience. It was published in the British journal *Heart*, and was entitled "Treatment of Cardiac Diseases: Evidence-Based or Experience-Based Medicine?"¹ This editorial

was written by Wolfgang Kubler of Heidelberg, Germany. The article stimulated me to reflect on what data I use to practice cardiovascular medicine. It made me realize that there is less evidence than I once thought and some of the evidence is fairly weak.

Several years ago I listened to a lecture by Dr. Richard Popp. The topic I have forgotten, but I do remember a slide in which he quoted the great cardiac surgeon, C. Walton Lilihei. Lilihei reportedly said that "all clinicians need good judgement. Good judgement comes from experience. Experience comes from bad judgement." As we look back on our careers as physicians, I think most will agree that there is a great deal of truth in that statement.

Most agree that randomized prospective controlled clinical trials stand at the top of the list for evidence-based medicine, surpassing cohort studies, case control studies, case reports, and so forth. If large randomized controlled trials are able to show prolongation of good quality life, whatever therapy was used should be considered in the patients who satisfy entry criteria. However, if five or six different agents are tested for the same condition and each shows a prolongation of life, to quote Kubler, "a survival rate of 100% or immortality would result." This, of course, is nonsense and indicates that patients who satisfy entry criteria are not a homogeneous population. A physician still must use judgement based on evidence but also on experience.

Treatment Based on Evidence

Several principles need to be considered when treatment is based on "evidence." One of the first principles relates to the use of optimum therapies. Patients in trials comparing one therapy with another,—for example, medical therapy with

revascularization therapy for ischemic symptoms—must receive appropriate aggressive medical therapy when randomized to either therapy. It is unlikely that this occurs in most instances. To illustrate, even in our most recent trials, medical therapy in general did not consist of maximum anti-anginal medication, protocol-driven antiplatelet therapy with aspirin or glycoprotein IIb/IIIa receptor blockers, hypertension control, diabetes control, lipid control, cessation of smoking, exercise programs, weight reduction, and so forth. Yet, in the year 2000, these are the therapies that we recommend to all of our patients with ischemic heart disease who are being treated with nonrevascularization strategies. Of course, in the patients randomized to revascularization (percutaneous transluminal coronary angioplasty or coronary artery bypass graft surgery), most did not receive stents, not all patients received internal thoracic artery bypasses, and beating heart surgery was not performed in any of the trials of which I am aware.

Another principle espoused by Kubler is that because megatrials consist of heterogeneous populations, whatever therapy is offered may be ineffective at best and detrimental at worst in some of these patients. Kubler argues that this is the reason that mortality in myocardial infarction is greater in field studies or in the general population than in the randomized controlled trials with carefully predefined selection criteria.² Commenting on concerns about megatrials and the issue of heterogeneity of patients, Maseri, in another editorial, made the point that

...if the pathogenic mechanisms of anemia were still as obscure as those of infarction, unstable angina, sudden death, [etc.] ... hematologists could design a megatrial enrolling 10,000 patients with hemoglobin levels < 10 g%: 5,000 randomized to treatment with vitamin B12 and 5,000 to placebo for 1 year. If a sufficiently large number of B12-deficient patients happened to be in the group, the statistical analysis of the results would demonstrate that after 1 year, treated patients on average had a highly significant increase in hemoglobin concentration... However, the average increase in hemoglobin would merely be the result of the benefit produced in B12-deficient patients.³

Is this "evidence-based" medicine? I don't think so!

Another principle that must be considered is the inadequate dosing of the therapy offered. It is common knowledge that the Studies of Left Ventricular Dysfunction (SOLVD) investigators strongly recommended higher doses of enalapril than are currently used in patients with heart failure. For some rea-

son, many physicians are timid when using potent clinically indicated pharmacologic agents such as angiotensin-converting enzyme (ACE) inhibitors, beta blockers, lipid-lowering agents, and so forth.

Another principle and clinical concern relates to duration of treatment. If a therapy seems to be working, how long should the treatment be continued? For example, how long should ACE-inhibitor therapy be continued in a patient after a myocardial infarction to prevent pathologic remodeling and dilation of the ventricle? When the ventricle heals and three to six months have passed, I suspect that the ventricle is fairly stable. Can the ACE inhibitor be discontinued at that point? Most studies are not carried out over long periods of time, and thus there are very few evidence-based data available to guide us in the long term. For example, if the study results were carried out over two years, there is no information beyond that. Common sense and clinical intuition based on symptoms and other objective findings in many instances should determine whether that patient is continued on the initially recommended therapy. I suspect that often patients are continued on the therapy despite the lack of evidence. Is this bad judgement? Perhaps!

Another principle relates to publication of results of clinical trials. It is much more likely that a trial with a positive result will be published and widely marketed by industry than will a negative trial. Kubler makes the point that the positive trial often is published in an English language journal and is frequently the subject of multiple publications espousing the positive results of that trial. One only has to look at one's desk to recognize that what Kubler says is correct. Practically every week something comes across the desk emphasizing results of a clinical trial that has shown efficacy in the recent past—most recently, two loose leaf binders containing data extolling the benefits of the glycoprotein IIb/IIIa receptor

blockers in the management of acute coronary syndromes. These publications included not only text, but slides, references, lecture notes, and so forth.

Finally, as I have said many times in the past, randomized prospective clinical trials are important to provide prognostic information in patient populations (not individuals) with cardiac disease. They are wonderful documents to provide us with guidelines for clinical practice. However, the physician must use these guidelines as adjuncts to clinical judgement, not recipes for making decisions in the individual patient. All physicians (me, included), want to practice evidence-based medicine, but in actual practice our decisions are not always based on hard evidence. If that ever occurs, there will be no need for judgement by physicians. Medicine will be carried out "by the book." As Kubler has pointed out, in daily routine practice, empirical criteria—including psychological, social, economic, medical, and technical factors—are at least equally important. I share his point of view. Thus, clinical judgements are based on whatever evidence exists, plus experience.

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