Confusing Press Releases and the PREVENT Study

To the Editor:

The Prospective Randomized Evaluation of the Vascular Effects of Norvasc Trial (PREVENT) was presented at the American Heart Association meeting >2 years before its publication.1 At that time, a lot of confusion and uncertainty was created by the press releases. Some authors stated, “In the 825-patient Prospective Randomized Evaluation of the Vascular Effects of Norvasc Trial (PREVENT), cardiovascular morbidity and mortality events were reduced by 31%. These events included heart attacks, strokes, deaths, angioplasty, bypass surgery, hospitalizations for severe angina, and heart failure.”2 Other authors seemed to disagree: “There was no difference in the overall mortality, in rate of heart attack or stroke, or in major vascular “events” between patients on amlodipine and those on an inert placebo—which was consistent with a lack of effect on the coronary arteries.”3 These seemingly contradictory statements made it exceedingly difficult for the practicing cardiologist to come to an objective conclusion.

Interestingly enough, now (2 years later) that we are able to scrutinize the study, both of these press releases seem to be “correct.” Thus, the seemingly irreconcilable difference in findings reflected in the press releases was just a matter of personal interpretation. However, such personal interpretations are of great concern when they occur among the same authors, in the same study, and at the same meeting and are reported to the news media and, thereby, to practicing physicians and patients. Authors should make an effort to come to a consensus before rushing to the news media and, if such a consensus cannot be reached, all publicity should be omitted.

Franz H. Messerli, MD
Ochsner Clinic and Alton Ochsner Medical Foundation
1514 Jefferson Highway
New Orleans, LA 70121

Response

We appreciate Dr. Messerli’s comments regarding the press releases for the Prospective Randomized Evaluation of the Vascular Effects of Norvasc Trial (PREVENT). One of the prespecified clinical end points in PREVENT was a combined end point that included death, nonfatal myocardial infarction, nonfatal stroke, hospitalization for angina pectoris, and the need for coronary revascularization. The press release from the Vancouver Health center was, therefore, correct in pointing out a significant reduction in cardiovascular events. However, as pointed out in our original presentation to the American Heart Association and in our article, this reduction in the combined clinical end point was almost entirely due to a reduction in hospitalization for angina pectoris and the need for coronary revascularization. Thus, the investigator-initiated Wake Forest University press release pointing out that there was no reduction in death, nonfatal myocardial infarction, or nonfatal stroke was an attempt to clarify this issue and provide clinicians with the most insightful information from our study. We would also like to emphasize that our study was not statistically powered to detect a reduction in death, nonfatal myocardial infarction, or nonfatal stroke, because the rate of these events was relatively low (~2% per year). Although there were no reductions in death, nonfatal myocardial infarction, or nonfatal stroke associated with the use of amlodipine in PREVENT, we think that the reduction in hospitalizations for angina pectoris and the need for coronary revascularization may have important implications for current practice.

Bertram Pitt, MD
Cardiology Division
Department of Internal Medicine
University of Michigan Medical Center
1500 East Medical Center Drive
3910 Taubman Center
Ann Arbor, MI 48109
bpitt@umich.edu

Robert P. Byington, PhD
Curt D. Furberg, MD, PhD
Donald B. Hunninghake, MD
G.B. John Mancini, MD
Michael E. Miller, PhD
Ward Riley, PhD
for the PREVENT Investigators
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Franz H. Messerli

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