founded by the fact that some patients had one leg randomized to receive active MIRE and the other leg randomized to receive placebo MIRE. In the majority of subjects, both legs received the same treatment, but, in any case, we have no reason to question the value of random assignment. In addition, all subjects in the Leonard study (3) had one leg in the active group and the other leg in the placebo group.

Finally, when peforming monofilament testing, we used the "yes-no" method of testing, which is equally accurate and faster than the "forced-choice" method (4). We concur with Dr. Burke that only valid and reliable testing methods should be used.

While it is disappointing to discover that a promising new treatment may not be effective, patient treatment should be based on credible evidence. We hope that more randomized, placebo-controlled studies are conducted to either support or refute the results of our study and to help determine the rightful place of MIRE in the treatment of patients with peripheral neuropathy.

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Ischemia Imaging and Plaque Imaging in Diabetes: Complementary Tools to Improve Cardiovascular Risk Management

Response to Raggi et al.

Here we respond to the review by Raggi et al. (1). We are concerned that the stated aims have not been fulfilled.

The American Heart Association (2) and the U.S. Preventative Task Force (3) have strongly discouraged coronary heart disease (CHD) screening in asymptomatic subjects with diabetes. Only one small randomized study has shown benefit from revascularization in asymptomatic subjects with diabetes screened for CHD (4). This study needs to be replicated in larger groups with rigorous analysis of the psychological and physical benefits and cost effectiveness. Screening guidelines should remain conservative until further studies show clear evidence of clinical benefit. Raggi et al. present no data to validate the algorithm presented in Fig. 1 in their review; this is based on opinion only.

Although subjects with diabetes may be at high CHD risk even when myocardial imaging for ischemia is negative, we would disagree with the statement that this lends support to the concept of refining risk stratification in diabetes using plaque imaging techniques. For instance, using carotid intima-media thickness in asymptomatic diabetic patients to identify candidates for angiography will lead to many invasive tests in which the likelihood of finding significant CHD is low. Some of these patients will have luminal atherosclerosis, but current CHD prevention guidelines in diabetes mandate aggressive medical therapy regardless of the results of additional investigation. A lower threshold for angiography based on carotid intima-media thickness for instance could result in angioplasty for lesions that are not producing symptoms, that are moderate in stenosis severity, and for which there is no known survival benefit of angioplasty over medical therapy alone. More information on this debate will be available when the Bypass Angioplasty Revascularization Investigation 2 Diabetes (BARI-2D) study reports.

Finally, the authors fail to make a clear distinction between subjects with and without CHD symptoms. Revascularization may be justified at low thresholds in symptomatic patients, whereas screening of asymptomatic subjects should be reserved for limited situations (2,3). We share the authors' desire to develop a better strategy to manage asymptomatic patients with diabetes and CHD, but how to do this remains unclear.

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