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Implantable Cardioverter–Defibrillators: Reply

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lieved to be logical have been disproved. Furthermore, these results were not consistent with findings from the Multicenter Automatic Defibrillator Implantation Trial II (MADIT-II) and the Defibrillators in Non-Ischemic Cardiomyopathy Treatment Evaluation (DEFINITE), in which patients with class III disease benefited at least as much, on a relative scale, as did those with class II disease. This issue remains unresolved.

Dr. Patwala and colleagues wonder whether amiodarone–digoxin interactions diminished survival in the amiodarone group. Although we did not record digoxin levels, the data and safety monitoring board monitored the trial carefully, and there were no adverse-event data to suggest such a problem in the amiodarone group. In addition, the mechanisms of death in the amiodarone group did not include a rise in the incidence of sudden death due to arrhythmia, which one might expect as a consequence of digoxin toxicity.

The final issue raised by these correspondents is that the frequency of beta-blocker use increased to a lesser extent in the amiodarone group than in the other groups during the trial. Although the increase over time was smaller, the rate of beta-blocker use was high in all trial groups. More important, those treated with amiodarone and beta-blockers had a slightly (not significantly) worse outcome than those in the amiodarone group who were not treated with beta-blockers, as shown in Figure 4 of our article. Thus, we maintain that amiodarone confers no survival benefit on patients when used for primary prevention.

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1. Mark DB, Nelson CL, Anstrom KJ, et al. Cost-effectiveness of ICD therapy in the Sudden Cardiac Death in Heart Failure Trial (SCD-HeFT). Presented at the American Heart Association 2004 Scientific Sessions, New Orleans, November 10–17, 2004. abstract.

DR. KADISH REPLIES: Dr. Nash notes that the median age of the patients in SCD-HeFT was about 60 years and thus suggests that extrapolating data from SCD-HeFT to the Medicare population may not be appropriate. It should be noted that other trials of

ICD therapy in patients with coronary disease, including the Multicenter Unsustained Tachycardia Trial¹ and MADIT-II,² involved patients with an average age that was closer to 65 and showed that ICD therapy was associated with a benefit similar to or greater than that seen in SCD-HeFT. In addition, there was no significant difference in the ICD-associated benefit between those 65 or older and those younger than 65 in SCD-HeFT and DEFINITE.³ As the average life expectancy approaches 80 years and as the quality of life among elderly patients increases, it would not be appropriate to withhold lifesaving therapy from patients older than 65 because of a preconceived notion that it will not offer them a benefit.

Dr. Mack performs an estimated cost-effectiveness analysis and concludes that ICD therapy will cost \$86,000 per year of life saved and that the amount spent on defibrillators means that other services will be withheld. A preliminary analysis of data from SCD-HeFT shows a much lower cost per life-year saved.⁴ Overall, Medicare spending is determined annually by Congress, and information on actual health care costs is available for budgeting. No hard ceiling on spending has been established. Finally, subgroup analysis or pooling of data is attractive to generate hypotheses but does not serve as an evidence-based approach to determine therapy. It is true that certain subgroups who benefit less than others from ICD implantation may be identified, and it is hoped that the prospective registry mandated by the Centers for Medicare and Medicaid Services will help provide additional information about which patients will benefit most from ICD therapy. However, before such data are available, the best guide for clinicians with regard to ICD implantation remains the inclusion criteria in clinical trials.

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1. Buxton AE, Lee KL, DiCarlo L, et al. Electrophysiologic testing to identify patients with coronary artery disease who are at risk for sudden death. *N Engl J Med* 2000;342:1937-45.

2. Moss AJ, Zareba W, Hall WJ, et al. Prophylactic implantation of a defibrillator in patients with myocardial infarction and reduced ejection fraction. *N Engl J Med* 2002;346:877-83.

3. Kadish A, Dyer A, Daubert JP, et al. Prophylactic defibrillator implantation in patients with nonischemic dilated cardiomyopathy. *N Engl J Med* 2004;350:2151-8.

4. Kadish A. Prophylactic ICD implantation in nonischemic dilated cardiomyopathy: evidence-based medicine. Presented at Heart Rhythm 2004: 25th annual sessions, San Francisco, May 19–22, 2004.