Reply

The letter by Latini and associates illustrates some of the problems associated with trials using a new antiarrhythmic drug. Studies such as they propose may provide useful data but unfortunately cannot safely be carried out in patients with life-threatening sustained ventricular tachyarrhythmia. Extrapolation of safety and efficacy data from patients with asymptomatic arrhythmia to patients with sustained arrhythmia is not always accurate because therapeutic plasma concentrations may differ between the two groups (1) and patients in the latter group are often more likely to develop cardiac and extracardiac adverse effects at effective plasma concentrations (2).

Several other questions raised by Latini et al. should also be addressed. Although the minimal follow-up in our study was only 1 month, as stated in our Methods section, only patients who died or who had the drug discontinued because of adverse effects were followed up for <14 months on amiodarone therapy. We agree that myocardial drug concentrations may correlate better with antiarrhythmic activity than with plasma concentrations, but serial cardiac biopsies are an impractical method by which to guide long-term outpatient therapy. Therapy was considered ineffective if a symptomatic sustained tachyarrhythmia occurred after the loading period. The plasma concentration at or nearest that event was used for analysis.

Ideal studies on new antiarrhythmic drugs with unusual pharmacokinetics like amiodarone are difficult to design. Although all clinical studies have inherent limitations as previously discussed, we believe that studies such as ours provide information relevant to treatment of patients with serious arrhythmias.

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References

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2. Morganroth J, Anderson JL, Gentzkow GD. Classification by type of ventricular arrhythmia predicts frequency of cardiac events from flecainide. J Am Coll Cardiol 1986;8:607–15.

Selection and Outcome of Patients Referred for Cardiac Transplantation

Evans and Maier (1) present an interesting analysis of the results of referral of patients to various medical centers for cardiac transplantation. One of the more striking findings in their study was the difference between centers in the percentage of patients accepted for transplantation (69.1% at the University of Pittsburgh versus 26.2% at Stanford University). In their discussion of these findings, the authors fail to point out probably the most salient explanation for these differences, namely, the mechanism for deciding whether a patient is acceptable for cardiac transplantation at a given institution. It would seem quite likely that the percentage of patients accepted would be higher at an institution where, for example, the cardiac surgeon receiving the referral was the only individual deciding on the suitability of transplantation, as opposed to a center where this decision is the joint responsibility of members of a committee comprising cardiologists, surgeons and other medical specialists. It would be of importance to know if the authors have any data pertaining to the method of selection at the institutions studied.

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References

1. Evans RW, Maier AM. Outcome of patients referred for cardiac transplantation. J Am Coll Cardiol 1986;8:1312–7.

Reply

Engel raises an important issue concerning the selection of heart transplant recipients. He suggests that programs that admit candidates for transplantation solely on the basis of the judgment of a cardiac surgeon are likely to have a higher acceptance rate than that of centers where a team of surgeons, physicians and other medical specialists determines the suitability of a patient referred for cardiac transplantation.

This hypothesis is not borne out by the data amassed during the conduct of the National Heart Transplantation Study (1). In Volume I of the study we describe at length each of the transplantation centers that participated in the study. It is noteworthy that both the Stanford University Medical Center and the University of Pittsburgh follow what might be referred to as a "team approach" to patient selection. To my knowledge, the majority of cardiac transplantation programs in the U.S. follow the team approach when selecting transplant candidates. This is particularly important given problems associated with the management of the patient after transplantation. Only in potentially dire circumstances might the need for a team evaluation be obviated by an aggressive surgeon. How frequently such circumstances may arise is difficult to judge based on our data.

In conclusion, therefore, we have no evidence to support Engel's hypothesis, nor do we know of the availability of such data. We remain convinced that the patient selection criteria a transplantation *team* chooses to adhere to are the major determinants of the case mix of patients who become candidates for transplantation in individual programs. Over the course of our study such criteria changed and it appeared that the Pittsburgh program was somewhat more lenient than the Stanford program in the selection of transplant recipients. Also, because the team approach to patient selection was a constant rather than a variable in our study, there was no need to examine it as an independent predictor of patient outcome, although it could be argued that the quality of team member interaction may vary across programs.

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Reference

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