of patients, we have had few serious adverse effects and none that have not responded to withdrawal of the drug. Fatal arrhythmias, decompensation of congestive heart failure, lupus erythematosus, blood dyscrasias, or liver dysfunction are not seen with oral amiodarone.

This impressive long-term safety record, unapproached by any standard antiarrhythmic agent available, is not derived from a small sample of patients over a brief period. The drug has been used extensively in Europe and South America during the past decade. In France alone, more than 240 million amiodarone tablets were prescribed between 1969–1977, amounting to over 500,000 patient-years of experience.

The authors of the present study have not related their experience with long-term amiodarone therapy; if they have new evidence to support their prescription against its extended use it should be reported. Otherwise, it may be performing a disservice to many patients who could benefit from a highly effective antiarrhythmic drug with an excellent safety record to condemn that drug for chronic use without supporting data.

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References


The authors reply:

Drs. Sobol and Rakita state that they have no objection to the design or the results of our study. They object, however, to a statement made at the end of our discussion that they feel is unsupported. This statement reads: “The drug probably should not be used orally for an extended time because of its side effects.” We then explain that “its application in chronic angina pectoris may be limited; however, the drug could be useful orally to control refractory arrhythmias.” Thus, we agree with Sobol and Rakita and with others that amiodarone may be very useful for the control of episodic and recurrent arrhythmias. We voiced a word of caution in the long-term treatment of angina pectoris for two reasons. First, we were aware from the extensive documentation supplied to us by Labaz Laboratories from Brussels, Belgium, of the side effects of the drug. We also realized that, as stated by Drs. Sobol and Rakita, they were usually reversible after withdrawal of the medication. However, we felt that a drug that has such profound effects on cardiac conduction (the occurrence of complete atrioventricular block is not mentioned by Sobol and Rakita), the eye, the thyroid gland and the peripheral nerves cannot be considered totally innocuous and should not be given indiscriminately for extended periods of time. Second, although amiodarone was introduced as an antianginal agent in Europe in 1967, we have the impression, from our discussions with French cardiologists, that its use for that indication has decreased progressively except, of course, for the short-term treatment of Prinzmetal’s angina, while its use for the treatment of arrhythmias is increasing. Our clinical experience with this drug in the United States and in Canada is obviously very limited. This and the fact that it is a unique pharmacologic agent has prompted us to undertake this study abroad with the collaboration of our colleagues in Lyon, France. Only time and clinical experience will tell us whether our prudence is excessive.

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Survival in Patients with Coronary Disease

To the Editor:

One of our colleagues in Seattle recently asked us why exertional hypotension during exercise testing did not appear as a variable predictive of survival in our article, “Variables Predictive of Survival in Patients with Coronary Disease” (Circulation 59: 421, 1979). Upon reviewing the raw data, we find that an error of omission has been made in table 2 on pages 424 and 425. Exertional hypotension, defined as systolic pressure during exercise testing lower than pretest systolic pressure, was univariately predictive of survival. Our data show that 5.8% (27 of 64) of the survivors had exertional hypotension, while 14.3% (eight of 56) of those who died had exertional hypotension in the medical cohort. This difference is statistically significant using the chi-squared analysis at the 5% level. The mortality rates were not significantly different at the 5% level among the medical cohort. Neither test showed significance for the surgical cohort.

However, exertional hypotension is not predictive of survival when examined in a multivariate fashion using stepwise discriminant analysis as shown in table 3 on page 425. This may have been due to the multivariate analysis also including maximal systolic blood pressure during exercise. Of course, exertional hypotension and maximal systolic blood pressure should be correlated. We are proceeding with further analysis to assess the prognostic significance of exertional hypotension in medically treated patients with coronary disease. However, we wish to call your readers’ attention to the fact that it is univariately predictive of survival in medically treated patients, but may carry similar prognostic information to other exercise test variables such as maximal systolic blood pressure, and therefore was insignificant in the stepwise discriminant analysis.

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Survival in patients with coronary disease.
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