THE EVALUATION OF NEW ANTIARRHYTHMIC DRUGS
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THE EVALUATION OF NEW ANTIARRHYTHMIC DRUGS


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P R E F A C E

In March of 1980, it was evident that a host of new antiarrhythmic agents were being evaluated in the United States and that most were proceeding down very different pathways in their process of evaluation. In part, this was due to a lack of preciseness of the Food and Drug Administration's guidelines for the evaluation of new antiarrhythmic agents and in larger part, to the different approaches of investigators who were usually infatuated with a particular model of study. Thus, the setting was ripe for similar antiarrhythmic agents to be studied using markedly different methods causing confusion and possible delay in their approval by the Federal Government for marketing. Pre-clinical animal models of a variety of types were utilized in different ways by different scientists as was the primary thrust of clinical evaluation with some centers being limited to invasive electrophysiologic studies while others used primarily noninvasive ambulatory monitoring and exercise testing models.

Since the United States' physicians have a rather limited drug armamentarium to treat patients with cardiac arrhythmias, we feel, as do others, that a concerted effort should be made to speed the process of obtaining approval of new antiarrhythmic agents. Such agents are needed not only for the treatment of patients with life-threatening ventricular arrhythmias but also, potentially most important, for the prophylaxis of sudden cardiac death in a high-risk population with electrical instability.
The following manuscripts represent the collective effort of physicians and scientists from the United States and abroad as well as members of the Food and Drug Administration and the pharmaceutical industry to address this problem. The state-of-the-art has been addressed by those active in a particular field in the individual manuscripts which are followed by topical discussions in which all participants were able to express their viewpoints about the important issues raised. While we did not anticipate that this Symposium would evolve a simplified methodology with unanimous consensus to evaluate a new antiarrhythmic agent, the Symposium did identify important research questions yet to be answered and has clarified particularly the inter-relationships between the different models of study in both the pre-clinical and clinical arenas. We hope that this book can be used as a reference for those individuals who design study protocols and define guidelines to determine the suitability of new antiarrhythmic agents for marketing.

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CONTENTS

Preface V
List of contributors XI

How to evaluate a new antiarrhythmic drug: The challenge of sudden cardiac death
J. Morganroth 1

Pre-Clinical Evaluation of a New Antiarrhythmic Agent

Relationships between effects on cardiac electrophysiology and antiarrhythmic efficacy
B.F. Hoffman 5

What animal models should be used to define antiarrhythmic efficacy: acute dog models?
L.S. Dreifus, M. Naito and E.L. Michelson 17

Description of chronic canine myocardial infarction models suitable for the electropharmacologic evaluation of new antiarrhythmic drugs
E.L. Michelson, J.F. Spear and E.N. Moore 33

Non-canine animal models for evaluating antiarrhythmic efficacy
E.N. Moore, J.F. Spear and E.L. Michelson 47

General Group Discussion: Animal Models 53

Defining the pharmacodynamics and pharmacokinetics of new antiarrhythmic drugs
R.E. Kates 69

General Group Discussion: Pharmacology 77

Chronic Studies in Patients with Non-Hemodynamically Significant Ventricular Arrhythmics

How should Holter monitoring analysis be performed?
C.L. Feldman 87

Long-term ambulatory electrocardiographic recording in the determination of efficacy of new antiarrhythmic agents
J. Morganroth 103

Evaluation of antiarrhythmic drugs. Should the Lown classification be used as a measure of efficacy?
R.W.F. Campbell 113

General Group Discussion: Holter Monitoring 123
Study Designs: Chronic Patients

Introduction
D.M. Krikler

New means of evaluating antiarrhythmic drugs
R. Temple

Parallel or crossover designs in evaluation of antiarrhythmic therapy
H.C. Kraemer

General Group Discussion: Study Designs: Chronic Patients
Remarks: J. Richard Crout, Director, Bureau of Drugs Food and Drug Administration

Acute Studies in Patients with Hemodynamically Significant Significant Ventricular Arrhythmias

Acute drug testing as a part of a systematic approach to antiarrhythmic drug therapy
P.J. Podrid

What is the role of electrophysiology in drug testing?
D.P. Zipes

General Group Discussion: Electrophysiology

What should the study design be to test new antiarrhythmic drugs in patients with acute myocardial infarction, digitalis toxicity and other acute problems
R.A. Winkle

General Group Discussion: Study Designs in Acute Patients

Special Considerations

What baseline electrophysiologic data should be obtained (plus discussion)
K. Rosen

Assessment of the hemodynamic and inotropic effects of antiarrhythmic drugs (plus discussion)
R.S. Aronson, S. Susskind and E.H. Sonnenblick

Evaluation of drug treatment in supraventricular arrhythmias (plus discussion)
E. Kaplinsky and L. Naggan

How should long-term safety of a new antiarrhythmic drug be defined (plus discussion)
J. Karliner
How should one manage emergency drug requests and their data (plus discussion)
   S.J. Ehrreich

How does one evaluate and use outside U.S.A. data in the new drug application (plus discussion)
   A. Watanabe

Index
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