Quality Control Measures in Long-Term Ambulatory Recordings

The adequacy of quality control is a basic tenet of any research endeavor. The definition of antiarrhythmic drug efficacy is based on quantitative data obtained by long-term electrocardiographic recordings. Three important elements of the quality control of such monitoring data include: 1) the adequacy of the recording instruments and the analyzer, 2) the quality of the data tape itself, and 3) the accuracy and repeatability of the analysis method. Quality control of the recorder and the analysis system requires careful attention to several technical components to ensure adequate recorder speed, frequency response of the instruments, synchronization of the ECG stylus, and linearity of the amplifiers. The data tape itself must be carefully scrutinized to determine that proper electrode application was performed to avoid excessive motion artifact and to ensure that the recorder was not faulty and that the battery had adequate power.

Quality control in the analysis of quantitative data is critically important in new antiarrhythmic drug research. This begins with the proper analyst training and certification. Details of the types of systems available for analysis are covered elsewhere in the Symposium. To maintain quality control one must be certain that known data tapes are employed to 1) evaluate waveform analysis routines on the instrument before data analysis commences, 2) that several 15-minute real-time analyses of each data tape are performed to test the software devices, 3) that the final data are verified...
by a cardiologist for algebraic and physiologic correctness, and 4) that repeatability and accuracy of the system be frequently measured. Repeatability is determined by re-introducing into the analysis system data tapes that have been previously analyzed. We recommend at least 2% of such tapes be reintroduced per month to determine adequate repeatability. Accuracy of the information must be obtained by introducing into the system "gold standard" data tapes which we define as those tapes analyzed in real-time in which the arrhythmia type and frequency have been verified by a cardiologist. Two percent of such tapes should be introduced into the analysis system every month to ensure data accuracy.

A standard quality control program for long-term ECG monitoring must be insured in new antiarrhythmic drug evaluation. Before a standard quality control system is developed and can be widely applied using a library of standardized long-term electrocardiographic data tapes, central dedicated research-oriented analysis services for long-term ECG monitoring data should be utilized. These services must demonstrate adequate quality control measures for cooperative clinical research trials. Individual investigator or hospital-oriented laboratory services without an adequate quality control program or a means of demonstrating accuracy and repeatability would be least desirable.

Definition of Antiarrhythmic Drug Efficacy by Long-Term Electrocardiographic Monitoring

The definition of antiarrhythmic drug efficacy in minimally symptomatic or asymptomatic patients has perplexed clinical investigators for many years. Prior determination of antiarrhythmic drug efficacy has used anecdotal judgment or the philosophical approach of Gallen which is embodied in the quote: "All those who drink from this remedy recover in a short time, except those in whom it does not help--who all die--therefore, it is obvious that it fails only in incurable cases". Today, with the availability of quantitative data