GROUP SEQUENTIAL METHODS FOR SURVIVAL ANALYSIS WITH STAGGERED ENTRY

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1. Introduction

In many clinical trials, especially in the study of chronic disease, we are often interested in the comparison of time to failure among different treatment groups. Many procedures have been developed in the past decade to analyze such failure time data, the most popular being the logrank test (Mantel, 1966; Peto and Peto, 1972) and modifications of the Wilcoxon test (Gilbert, 1962; Gehan, 1965; Breslow, 1970; Peto and Peto, 1972; Prentice, 1978).

Typically in such a trial, patients enter the study serially, are then assigned according to some random mechanism to different treatment arms and are followed until they either fail or the study is terminated. Ordinarily, these studies are designed so that after sufficient amount of patient accural and follow-up time a single terminal analysis will be made to ʻest whether the failure time distribution is the same among the different treatment groups. In practice, however, as well as for ethical considerations, the data are monitored periodically and if sufficient differences are found between the treatment groups, a decision might be made to stop the study early. It is, therefore, very important to study the sequential properties of the tests used in survival analysis in order that correct and efficient methods be employed in monitoring the data.