DESIGN AND ANALYSIS OF CROSSOVER CLINICAL TRIALS WITH CENSORED SURVIVAL DATA

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Francis, Lewis and Kay (1991) and Feingold and Gillespie (1996) reported an analysis of a set of survival data from crossover clinical trials. This paper proposes a combination of the standard analysis of data from a 2×2 crossover clinical trial, the so-called two-stage procedure, and a technique of nonparametric survival function estimation with doubly censored survival data. Such right-censored and left-censored data arise in crossover clinical trials when differences of the two varying survival times from each patient are obtained. The maximum likelihood estimate of the survival function, based on the self-consistency algorithm proposed by Turnbull (1974), can be computed and the comparison of several survival curves is done by a generalization of the log-rank test. The performance of this methodology is compared with those of the previously proposed methods in a simulation study. Sample sizes determination is discussed for a future planning of crossover clinical trials.