

# Statistical analysis of illness death processes and semi-competing risks data by

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## **Abstract**

Semi-competing risks data frequently arise in clinical and observational studies where the subject can experience events of two different types and a terminal event (e.g., death) censors a non-terminal event (e.g., relapse) but not vice versa. Such data were previously analyzed by postulating that the joint survival function of two event times follows a copula with two margins in the observed upper wedge. The approach is similar to, but under weaker assumptions than that of the latent failure times in competing risks data. The interpretation of the marginal distribution of the non-terminal event is quite controversial which further complicates the incorporation of the covariance analysis. In this article, we propose an illness-death model for semi-competing risks data which nicely fit the data structure and easily entails the covariance analysis. Nonparametric maximum likelihood estimation is used for inference and a simple and fast algorithm is developed for its numerical implementation. The maximum likelihood estimators for the regression coefficients and the dependence parameter are shown to be consistent and asymptotically normal, and their asymptotic variances attain the semi-parametric efficiency bound. The proposed method is illustrated with an analysis of data from a randomized clinical trial of nasopharyngeal cancer. Simulation studies are used to evaluate its finite sample performance.

This is a joint work with John D. Kalbfleisch at University of Michigan and Beechoo Tai at National University of Singapore.