Graphically Presenting the Treatment Effect via Semiparametric Analysis for Survival Data

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Abstract

For clinical trials with survival data, the hazard ratio has been the most widely used measure for describing the treatment effect. When there is possibly a treatment by time interaction, the hazard ratio may be less than one in a region where there is no improvement in the survival experience. While there have been various measures such as risk ratio that relate more directly to the survival experience, they are mostly studied non-parametrically and in separation. The short-term and long-term hazard ratio model of Yang and Prentice (2005) contains the proportional hazards model and the proportional odds model as sub-models, and do not have restrictions such as zero or infinite hazard ratio in the short term or long term, that many other semi-parametric models impose. We investigate various measures under the short-term and long-term hazard ratio model. Their estimates, point-wise confidence intervals and simultaneous confidence bands are established. These confidence intervals and confidence bands can be used to capture and to graphically present the treatment effect. We illustrate these visual tools and discuss their merits and limitations in applications to clinical trials including the Women's Health Initiative.

Keywords: Clinical trials; Survival data; Treatment effect; Treatment-time interaction; Confidence bands.

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