

Competing Risk Analyses in Survival Trials During COVID-19 Pandemic

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Abstract : In the presence of competing events, traditional survival analysis may not be appropriate and can result in biased estimates, as it assumes independence between competing events and the event of interest. Instead, competing risk analysis should be considered to correctly estimate the survival probability of the event of interest and the hazard ratio between treatment groups. The COVID-19 pandemic has provided a potential source of competing risks in clinical trials, as participants in trials may experience COVID-related competing events before the occurrence of the event of interest, for instance, death due to COVID-19, which can affect the incidence rate of the event of interest. We have performed simulation studies to compare multiple competing risk analysis models, including the cumulative incidence function, the sub-distribution hazard function, and the cause-specific hazard function, to the traditional survival analysis model under various scenarios. We also provide a general recommendation on conducting competing risk analysis in randomized clinical trials during the era of the COVID-19 pandemic based on the extensive simulation results.

Keywords : competing risk, survival analysis, simulations, randomized clinical trial, COVID-19 pandemic

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