

Group Sequential Analysis based on RMST

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Abstract: It is appealing to compare survival analysis based on restricted mean survival time (RMST), since it generates a clinically interpretable summary of the treatment effect, which can be estimated nonparametrically without assuming restrictive assumptions such as the proportional hazards assumption. However, there are special challenges in designing and analyzing group sequential study based on RMST, because that the truncation timepoint of the RMST in the interim analysis often differs from that in the final analysis. A valid test controls the unconditional type one error has been developed in the past. However, there is no appropriate statistical procedure for constructing the confidence interval for the treatment effect measured by the contrast in RMST, while it is crucial for informative clinical decision making. In this talk, we will discuss how to construct confidence intervals for the difference RMST in a group sequential setting. Examples and numerical studies will be presented to illustrate the method.