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May 20
Thursday
9-10am EST

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Title

On information fraction for Fleming-Harrington type weighted logrank tests in a group-sequential clinical trial design

Abstract

When comparing survival times of treatment and control groups under a more realistic nonproportional hazards scenario, the standard logrank (SLR) test may be replaced by a more efficient weighted logrank (WLR) test, such as the Fleming-Harrington (FH) test. Designing a group-sequential clinical trial with one or more interim looks during which an FH test will be performed, necessitates correctly quantifying the information fraction (IF). For SLR test, IF is defined simply as the ratio of interim to final numbers of events; but for FH test, it can deviate substantially from this ratio. In this presentation, we separate the effect of weight function (of FH test) alone on IF from the effect of censoring. We have shown that, without considering the effect of censoring, IF can be derived analytically for FH test using information available at the design stage and the additional effect due to censoring is relatively smaller. This presentation intends to serve two major purposes: first, to emphasize and rationalize the deviation of IF in weighted logrank test from that of SLR test which is often overlooked; second, although it is impossible to predict IF for a weighted logrank test at the design stage, our decomposition of effects on IF provides a reasonable and practically feasible range of IF to work with. We illustrate our approach with an example and provide simulation results to evaluate operating characteristics.

Professional Biography

Dr. Madan G. Kundu is an Associate Director, Biostatistics, in the Cancer Enterprise division at Daiichi Sankyo Inc. He received his Ph.D. in Biostatistics from the Indiana University in 2014. Prior to joining Daiichi Sankyo in 2020, he worked at Novartis Oncology and AbbVie Inc. He has supported drug development as Statistician in the therapeutic area of, including but not limited to, breast cancer, glioblastoma, non-small lung cancer, neuro-endocrinal tumor, and acute leukemia. His research interest includes delayed treatment effect, CART based tree methods, quantitative decision making, dose titration designs, and functional data analysis.

Sponsored by

- American Statistical Association (Boston, Connecticut, Florida, New Jersey, Princeton/Trenton, and Washington chapters)
- Boehringer Ingelheim Pharmaceuticals, Inc. (Biostatistics and Data Sciences Department)
- New England Statistical Society (NESS)

For interested participants

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