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Group Sequential Covariate-Adjusted Response Adaptive Designs for Survival Outcomes

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Abstract : Driven by evolving FDA recommendations, modern clinical trials demand innovative designs that strike a balance between statistical rigor and ethical considerations. Covariate-adjusted response-adaptive (CARA) designs bridge this gap by utilizing patient attributes and responses to skew treatment allocation in favor of the treatment that is best for an individual patient's profile. However, existing CARA designs for survival outcomes often hinge on specific parametric models, constraining their applicability in clinical practice. In this article, we address this limitation by introducing a CARA design for survival outcomes (CARAS) based on the Cox model and a variance estimator. This method addresses issues of model misspecification and enhances the flexibility of the design. We also propose a group sequential overlapweighted log-rank test to preserve type I error rate in the context of group sequential trials using extensive simulation studies to demonstrate the clinical benefit, statistical efficiency, and robustness to model misspecification of the proposed method compared to traditional randomized controlled trial designs and response-adaptive randomization designs.

Keywords : cox model, log-rank test, optimal allocation ratio, overlap weight, survival outcome
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