

Statistical Inference for Covariate-Adaptive Randomization Procedures

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Abstract: Covariate-adaptive randomization (CAR) procedures are frequently used in comparative studies to increase the covariate balance across treatment groups. However, because randomization inevitably uses the covariate information when forming balanced treatment groups, the validity of classical statistical methods after such randomization is often unclear. In this article, we derive the theoretical properties of statistical methods based on general CAR under the linear model framework. More importantly, we explicitly unveil the relationship between covariate-adaptive and inference properties by deriving the asymptotic representations of the corresponding estimators. We apply the proposed general theory to various randomization procedures such as complete randomization, rerandomization, pairwise sequential randomization, and Atkinson's DA-biased coin design and compare their performance analytically. Based on the theoretical results, we then propose a new approach to obtain valid and more powerful tests. These results open a door to understand and analyze experiments based on CAR. Simulation studies provide further evidence of the advantages of the proposed framework and the theoretical results.