Abstract:
When conducting a randomized clinical trial, researchers' general goal is to obtain comparable treatment arms with respect to baseline characteristics. In order to examine this comparability (or lack thereof), investigators will oftentimes test for statistically significant differences across arms, and present their corresponding p-values in the familiar "Table 1" when reporting the trial results. This discussion strives to uncover some common misconceptions regarding the interpretation of these baseline test results in determining the "success" of a given trial's observed randomization scheme. We will explore the relationship between baseline variable imbalance and relevant statistical parameters (power, type I error rate, and bias) for final and interim analyses under several scenarios. Recommendations for evaluating influence of this baseline imbalance on overall trial statistical analyses and inferences will be provided.