PUBLIC HEALTH & PREVENTIVE MEDICINE

Grand Rounds

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The Analysis of Non-Inferiority Trials in the Presence of Non-Compliance

ABSTRACT

Most randomized clinical trials aim to demonstrate superiority of an experimental treatment relative to a standard treatment or placebo. An increasing number of trials, however, are focused on showing that the effect of the experimental therapy is *non-inferior* to the standard. This goal is of interest when the new therapy offers potential benefits such as reduced toxicity, invasiveness, or cost. In non-inferiority trials, the standard intent-to-treat (ITT) approach can result in invalid inferences about treatment effects in the presence of non-compliance. The per-protocol (PP) analysis has therefore been widely recommended as an additional analytic strategy for non-inferiority trials, but is also known to result in biased estimates of treatment effects. We consider causal modeling and instrumental variables as an alternative approach and compare its performance with that of the ITT, PP, and As-treated methods under different patterns of non-compliance that may be commonly observed in the non-inferiority trial setting

Food and beverages will be provided.

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