Statistical Remedies for Flawed Conventions in Medical Research

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Abstract

Many statistical methods commonly used for clinical trial design or data analysis in medical research have very undesirable properties that are not obvious, and that often are not well understood. In many cases, a flawed statistical convention may result in an incorrect inference that misleads practicing physicians to make poor therapeutic decisions. In this talk, I will describe examples of several such problems, and provide a practical alternative for each. As time permits, examples will include (1) how misinterpretation of p-values can lead to flawed conclusions, (2) consequences of failure to randomize or correct for selection bias when making treatment comparisons, (3) futility monitoring rules that do not work, (4) counterintuitive relationships between early response rate and mean survival time, (5) Simpson's Paradox and latent variable effects, (6) consequences of ignoring patient heterogeneity, (7) how conventional phase I dose-finding methods may cripple a new treatment in early phase clinical evaluation.