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Format: Abstract

[Stat Med.](#) 1995 May 15-30;14(9-10):925-32; discussion 933.

Estimating the minimum therapeutically effective dose of a compound via regression modelling and percentile estimation.

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Abstract

Estimation of the minimum effective dose (MED) of a compound from a typical placebo-controlled dose-response study can be carried out in several ways. Current approaches compare treatment doses against a placebo dose via selected contrasts to determine the lowest dose level at which the contrast is statistically significant. Ruberg shows how this approach works for various choices of contrasts. Instead, the MTED (minimum therapeutically effective dose) might be defined as the lowest dose level that yields a therapeutic benefit to patients, on average, or to a given percentage of patients. One could use a lower confidence limit for the mean approach to determine the dose yielding (on average) a therapeutic benefit via regression modelling of the continuous treatment dose response. More importantly, a patient relevant approach would be to actually estimate regression percentiles or construct regression tolerance intervals. Such an approach addresses the question 'What percentage of patients are receiving therapeutic (yet safe) doses', instead of just knowing that a dose is effective 'on average', and thus would help to understand the distribution of patient responses at a given treatment dose. This further enables one to better evaluate the efficacy versus safety trade-off as dose increases and provides better guidelines for prescribed dose levels.

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