

Sequential Conditional Probability Ratio Test: An Ideal Design for Clinical Trials?

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The sequential designs of clinical trials allow a trial to be stopped early when data collected at an early stage of the trial have produced enough, in one sense or another, evidence for the conclusion of testing about the hypotheses. Different sequential designs are available for the same requirement of significance level and power. On the other hand, the same set of observed data can be interpreted as outcomes of different sequential designs with the same significance level and power. For an observed data, the conclusion of a test may be significant by one sequential design but insignificant by another. This phenomenon may lead to the question that whether applying sequential test design to clinical trials is rational. Withstanding this challenge, the sequential conditional probability ratio test (SCPRT) offers a special feature: a conclusion made at an early stopping is unlikely to be reversed if the trial were not stopped but continued to the planned end. The SCPRT gives a sound reason to stop a trial early: if the trial were not stopped as it should be, adding more data and continuing the trial to the planned end would not change the conclusion. With an SCPRT procedure, a sequential clinical trial is designed with not only given significance level and power, but also with a given probability of discordance, by which the inconsistency of conclusions at different stages of the trial can be controlled to a minimum level.

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