





講 題:Statistical considerations and performance evaluation in mouse tumor models

- 主講人:陳曉倩 助理教授 (Department of Biostatistics, Vanderbilt University Medical Center)
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Mouse tumor volume measurements in preclinical studies are typically collected at regular intervals (equally spaced) or at least twice weekly (unequally spaced). A commonly used summary metric to evaluate drug efficacy is the treatment-to-control (T/C) ratio, which compares tumor volumes in treated (T) versus control (C) groups at a specific time point (Wu, 2010; Hather et al., 2014). Traditional statistical approaches, such as the two-sample t-test (a special case of ANOVA) or the Wilcoxon rank-sum test, are often applied at selected time points to assess treatment effects.

In this study, we compare the performance of several statistical methods for analyzing tumor volume data from xenograft experiments. Specifically, we evaluate both ratio-based T/C methods (tumor volume ratio) and rate-based T/C methods (tumor growth rate ratio), alongside the rate-based t-test, independent two-sample t-test, linear regression, and mixed-effects models. Simulated datasets were generated using a linear mixed-effects model, with parameters informed by two real-world tumor growth models.

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Our evaluation focuses on Type I error rate, statistical power, and coverage probability for detecting treatment effects at a 0.05 significance level. Results indicate that ratio-based T/C methods tend to inflate Type I error rates. Mixed-effects models demonstrate robust performance when their assumptions are met and outperform the other methods. However, the rate-based t-test may serve as an alternative when sample sizes are sufficiently large, as determined through power analysis in consultation with a statistician.