



# 大阪医学統計学セミナー 第70回

Osaka Biostatistics Seminar

9月27日 (水)  
15:30~17:00

「 Inference for Cumulative Incidences and Treatment Effects in Randomized Controlled Trials with Time-to-Event Outcomes under ICH E9 (E1) 」

Speaker : Yuhao Deng (Peking University)



場所 :  
医学系研究科基礎研究棟L階  
医学統計学研究室  
オンライン開催

参加ご希望の方は、前日までに下記  
問い合わせ先にメールにてお申込み  
ください。

Abstract: In randomized controlled trials (RCT) with time-to-event outcomes, intercurrent events occur as semi-competing/competing events, and they could affect the hazards of outcome or render the outcome ill-defined. Although five strategies have been proposed in ICH E9 (R1) addendum to address the intercurrent events in RCT, they did not readily extend to the context of time-to-event data for studying causal effects using rigorously stated assumptions to conduct causal analysis. In this study, we show how to define, estimate, and infer the time-dependent cumulative incidence of outcome events in such contexts for obtaining causal interpretations. Specifically, we derive the mathematical forms of the scientific objective (ie, causal estimands) under the five strategies and clarify the required data structure to identify these causal estimands. Furthermore, we summarize estimation and inference methods for these causal estimands by adopting methodologies in survival analysis, including analytic formulas for asymptotic analysis and hypothesis testing. We illustrate our methods with the LEADER Trial on investigating the effect of liraglutide on cardiovascular outcomes. Our study provides technical guidance on addressing intercurrent events in RCT with time-to-event outcomes. Studies of multiple endpoints and combining strategies to address multiple intercurrent events can help practitioners understand treatment effects more comprehensively.

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