大阪医学統計学セミナー 第66回

Osaka Biostatistics Seminar

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15：00〜16：15

「Frequentist analysis of basket trials with one-sample Mantel-Haenszel procedures」

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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

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Abstract :
  Recent substantial advances of molecular targeted oncology drug development are requiring new paradigms for early-phase clinical trial methodologies to enable us to evaluate efficacy of several subtypes simultaneously and efficiently. The concept of the basket trial is getting of much attention to realize this requirement borrowing information across subtypes, which are called baskets. Bayesian approach is a natural approach to this end and indeed the majority of the existing proposals relies on it. On the other hand, it required complicated modelling and may not necessarily control the type 1 error probabilities at the nominal level. In this paper, we develop a purely frequentist approach for basket trials based on one-sample Mantel-Haenszel procedure relying on a very simple idea for borrowing information under the common treatment effect assumption over baskets. We show that the proposed Mantel-Haenszel estimator for the treatment effect is consistent under two limiting models of the large strata and sparse data limiting models (dually consistent) and propose dually consistent variance estimators. The proposed estimators are interpretable even if the common treatment effect assumptions are violated. Then, we can design basket trials in a confirmatory matter. We also propose an information criterion approach to identify effective subclasses of baskets.

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