Yale SCHOOL OF PUBLIC HEALTH
Biostatistics

Subgroup Treatment Effect: One Selected Subgroup, Two Trials, and Three Evaluations

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ABSTRACT

When a promising subgroup is identified from an unsuccessful trial with a broad target population, we often need to evaluate and possibly confirm the selected subgroup with a follow-up trial. A direct evaluation of the subgroup from the subjects in both trials is not recommended because of the risk of data snooping. An evaluation based solely on the validation trial is free of bias, but does not make full use of the data in the earlier trial. We show that it is possible to utilize data from both trials to improve the efficiency of post-selection subgroup evaluation. In particular, we propose a new resampling-based approach to quantify and remove selection bias and then to perform data combination from both trials for valid and efficient evaluation of the subgroup effect. The proposed method is model-free and asymptotically sharp. We demonstrate the merit of the proposed method by revisiting the panitumumab trial and show how much data combination could help improve efficiency of clinical trials when a promising subgroup is identified post hoc from part of the data. This talk is based on joint work with Xinzhou Guo (Harvard University) and Jianjun Zhou (Yunan University).