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Subgroup Analyses: Exploring Stratification Strategies for Population- vs. Randomization-Based Inference

Monday, 16 September 2024 12:00 (30 minutes)

Stratification on important variables is a common practice in clinical trials,
since ensuring cosmetic balance on known baseline covariates is often deemed to be a crucial requirement for the credibility of the experimental results. However, the actual benefits of stratification are still debated in the literature. Other authors have shown that it does not improve efficiency in large samples and improves it only negligibly in smaller samples. This paper investigates different subgroup analysis strategies, with a particular focus on the potential benefits in terms of inferential precision of pre-stratification versus both post-stratification and post-hoc regression adjustment. For each of these approaches, the pros and cons of population-based versus randomization-based inference are discussed. The effects of the presence of a treatment-by-covariate interaction and the variability in the patient responses are also taken into account. Our results show that, in general, pre-stratifying does not provide substantial benefit. On the contrary it may be deleterious, in particular for randomization-based procedures in the presence of a chronological bias. Even when there is treatment-by-covariate interaction, pre-stratification may backfire by considerably reducing the inferential precision.

Type of presentation

Talk

Classification

Both methodology and application

Keywords

Regression adjustment, Randomization tests, Chronological bias

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Session Classification: SIS Invited session: Stratification, subsampling, randomization,issues and proposals

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