Cross-sectional design with a short-term follow up for prognostic imaging biomarkers

Ying Lu, Ph.D.

Department of Biomedical Data Science, Stanford University

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ABSTRACT:

Medical imaging techniques are being rapidly developed and used for diagnosis and prognostic predictions. To establish a prognostic predictive utility of a new imaging marker, a temporal association needs to be established to show an association between its baseline value with a subsequent chance of having the relevant clinical outcome. Validation of such techniques has several difficulties. First, different from techniques based on blood or tissue specimen, imaging techniques often have no historical samples to study and require new studies to collect data. For rare events, it can be costly. Second, the rapid technology evolution requires such validation studies to be short in order to keep the evaluation relevant. A new statistical design is proposed that extends traditional prospective cohort study by adding cases with known time of events and including a short-term follow-up to estimate the prospective odds ratio for the clinical endpoint of interest within a reasonably short duration of time. In this talk, we discuss two approaches using this design under either a mixed random effects model of continuous marker measurements or a Markov model for binary biomarker status to illustrate that this new design can deliver a consistent estimate of the odds ratio and a formula for asymptotic variance. Numerical studies suggest that the new design induces a smaller variance than the corresponding prospective cohort study within three follow-ups. Examples of imaging markers for Alzheimer’s disease data and Multiple Sclerosis (MS) demonstrated that the proposed design has a potential to be useful to rapidly establish a prognostic validity of a new imaging marker within a reasonable time, with a small sample size.

This is a joint work with Professor Joong-Ho Won at Seoul National University, Mr. Xiao Wu at Harvard University, Dr. Sang Han Lee at the Nathan S. Kline Institute for Psychiatric Research, and Professor Roland Henry at UCSF.

Reference: