





術 演

題: A flexible method for diagnostic accuracy with 講

biomarker measurement error

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Abstract

Diagnostic biomarkers are often measured with errors due to imperfect lab conditions or analytic variability of the assay. The ability of a diagnostic biomarker to discriminate between cases and controls is often measured by the area under the receiver operating characteristic curve (AUC), sensitivity, specificity, among others. Ignoring measurement error can cause biased estimation of a diagnostic accuracy measure which results in misleading interpretation of the efficacy of a diagnostic biomarker. Existing assays available are either research grade or clinical grade. Research assays are cost effective, often multiplex, but they may be associated with moderate measurement errors leading to poorer diagnostic performance. In comparison, clinical assays may provide better diagnostic ability, but with higher cost since they are usually developed by industry. However, diagnostic companies often are not interested in investing until an adequate diagnostic performance is observed. Therefore, a significant challenge is to select biomarker candidates for further development when their potentials are not fully observed while only research assays with varying analytical variability are available. The correction for attenuation approach often valid when biomarkers are from a normal distribution but may be biased with skewed biomarkers. In this paper, we develop a flexible method based on skew--normal biomarker distributions to correct for bias in estimating diagnostic performance measures including AUC, sensitivity, and specificity. Our new method improves on existing methods by allowing for skewed biomarker data and can be applied to evaluate the diagnostic efficacy of clinical assays in comparison with research assays. Finite sample performance of the proposed method is examined via extensive simulation studies. The methods are applied to a pancreatic cancer biomarker study.

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