Assessing Genomic Biomarker's Clinical Utility for Drug Development Versus for Clinical Management

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Abstract

With the advent of personalized medicine, genomic classifiers developed based on high throughput biotechnology such as microarrays or genome-wide single nucleotide polymorphism arrays raise the hope of yielding diagnostic tests that may help identifying high risk patients or likely responders. These clinical utilities may be assessed in randomized controlled trials for prospective patient subset identification or in postmarketing trials for selecting optimum treatment strategies for clinical management. Therefore, it is critically important that a predictive model developed demonstrates its context of use for drug development versus for the actual gain in predictive ability over the readily available clinical models. In this work, we compare the prediction performances under different risk/response scenarios with different prevalence. Results from simulation studies will be discussed. We show that the effective use of clinical model for clinical management depends on the particular cutoff for which the genomic classifier is constructed. This highlights the challenges in developing genomic models in the area of personalized medicine.

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