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The use of nomogram predictions as comparators in a phase II prostate cancer adjuvant treatment trial

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Phase II trials often use dichotomous clinical outcomes as efficacy endpoints. The trials are typically designed with hypothesized population values for the endpoints of interest; and, comparison of observed outcomes with population values are often utilized to justify further clinical testing. However, in the Phase II setting with relatively small sample sizes, hypothesized population values for endpoints of interest might be informatively modified by incorporation of individual patient data. For example, nomograms are widely used for predicting clinical outcomes in prostate cancer patients based on relevant clinical characteristics, yielding theoretical comparators for treatments of interest. In this article, we illustrate a novel use of nomogram predictions as comparators to evaluate the efficacy of an adjuvant multimodality therapy in a Phase II trial of patients at high risk for recurrence after radical prostatectomy. In this method, we describe individual outcomes as independent Bernoulli random variables, with probabilities of failure given from the nomogram. The total number of observed treatment failures therefore follows a null distribution which is a convolution of independent, non-identically distributed random variables. This distribution can be easily computed using probability generating functions which facilitates statistical assessment of the trial outcomes. We find that the adjuvant multimodality therapy significantly increased the proportion of progression-free individuals, relative to the nomogram predictions. We urge the continued use of the new approach, particularly with relatively small sample sizes as are commonly encountered in phase II trials for prostate cancer.

Biography

Zhenyu Jia has received his Ph.D. in Genetics, Genomics & Bioinformatics and a Master degree in Statistics in 2006 at University of California Riverside. After graduation, he was chosen to be the Principal Biostatistician and Bioinformatician in UCI SPECS consortium. He has published 20 papers in reputed journals, served as reviewer for more than 20 journals, and serve as an editorial member for the Journal of Data Mining in Genomics & Proteomics.

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