ANALYSIS METHODS OF MULTIPLE ENDPOINTS OF VARIOUS DATA TYPES IN COMPARATIVE CLINICAL TRIALS

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Treatment comparisons in clinical trials often involve several endpoints of equal clinical importance and one is faced with a need for an overall testing by considering the multivariate features of the treatment effects. O´Brien (1984) proposed the OLS and GLS statistics for continuous multiple endpoints. Pocock et. al. (1987) mentioned the possibility of simultaneously analyzing two or more endpoints of different data types such as quantitative, binary and survival data types; however, neither practical hints of how to combine several different types of endpoints in forming the OLS and GLS statistics were given, nor a simulation study conducted in order to assess the efficiencies of the OLS and GLS statistics for these situations. We propose a new method of testing multiple endpoints. First of all, obtain the p-values from a univariate analysis of each endpoint which might be of different data type and then combine these p-values. Unlike in the situation of meta-analysis, these p-values are correlated and have to be combined by considering correlatedness among them. The efficiencies of this method with those of OLS and GLS statistics are compared with a simulation study for multivariate normal data, of which some are dichotomized or transformed into ordinal scales. The proposed test statistic is shown to increase the power considerably without inflating the type I error for all situations. This method of testing can be used for any number and type of endpoints.