ROBUST TESTS IN GROUP SEQUENTIAL ANALYSIS: ONE- AND TWO-SIDED HYPOTHESES IN THE LINEAR MODEL

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Abstract. Consider the linear model $Y = X\theta + E$ in the usual matrix notation where the errors are independent and identically distributed. We develop robust tests for a large class of one- and two-sided hypotheses about θ when the data are obtained and tests are carried out according to a group sequential design. To illustrate the nature of the main results, let $\hat{\theta}$ and $\tilde{\theta}$ be an M- and the least squares estimator of θ respectively which are asymptotically normal about θ with covariance matrices $\sigma^2(X^tX)^{-1}$ and $\tau^2(X^tX)^{-1}$ respectively. Let the Wald-type statistics based on $\hat{\theta}$ and $\tilde{\theta}$ be denoted by RW and W respectively. It is shown that RW and W have the same asymptotic null distributions; here the limit is taken with the number of groups fixed but the numbers of observations in the groups increase proportionately. Our main result is that the asymptotic Pitman efficiency of RW relative to W is (σ^2/τ^2). Thus, the asymptotic efficiency-robustness properties of $\hat{\theta}$ relative to $\tilde{\theta}$ translate to asymptotic power-robustness of RW relative to W. Clearly, this is an attractive result since we already have a large literature which shows that $\hat{\theta}$ is efficiency-robust compared to $\tilde{\theta}$. The results of a simulation study show that with realistic sample sizes, RW is likely to have almost as much power as W for normal errors, and substantially more power if the errors have long tails. The simulation results also illustrate the advantages of group sequential designs compared to a fixed sample design, in terms of sample size requirements to achieve a specified power.

Key words and phrases: Clinical trial, comparison of two treatments, composite hypothesis, inequality tests, interim analysis, long tailed distribution, M-estimator, Pitman efficiency, power-robustness, repeated tests, Wald-type statistics.