SIMULTANEOUS COMPARISONS OF ACCURACY, SENSITIVITY, AND SPECIFICITY IN DIAGNOSTIC TRIALS: CLOSED TEST PROCEDURES WITH A-PRIORI ORDERED HYPOTHESES

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A diagnostic test is a procedure to increase the probability of a correct diagnosis in diseased and non-diseased patients. Dependent on the aim of the study, it may be necessary to include diseased and non diseased patients or patients with diseased and non diseased vessel segments (clustered data) into the clinical study population.
The most widely used measurement of performance of a diagnostic test is the accuracy, an overall or summary index of validity.
Often, the sample sizes of diseased and non diseased patients or vessel segments are markedly unbalanced. Because some definitions of accuracy are highly dependent on the sample size distribution in the subgroups, different results may be observed in a treatment comparison. The different accuracy indices in the literature are weighted means similar to the weighted means in a linear cell means model as introduced by Searle (1987) .
It is fully recognized, that subgroup analysis like the comparison of sensitivity in the subgroup of diseased and specificity in the subgroup of non diseased patients plays an important role in demonstrating the efficacy of a new diagnostic agent in confirmatory trials.
The problem of adjusting for multiple comparisons is described in Maurer et al.(1995). If the overall treatment effect the accuracy- is significant, suggesting that the treatment has an effect in some patients, then it is reasonable to perform subgroup analyses to identify those patients for whom the treatment is more beneficial (see P.E. Scoot and G. Campbell,1998).