TYPE I ERROR IN THE MCNEMAR'S TEST APPLIED TO THE LAB-DRIVEN MEDICAL DIAGNOSIS IN THE PRESENCE OF MULTIPLE MEASUREMENT ERRORS AND DETECTION LIMIT.

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The main goal of the research project is to evaluate the sensibility of the McNemar's test in terms of sensitivity with respect to: (i) the variance of the measurement errors, (ii) and detection limit. It was assumed that dichotomous medical diagnosis were based on the continuous and numerical results from the two laboratories. Due to the determination process the sample can be subject to the independent additive and proportional errors and detection limit as well. To correct for such problems, we proposed a 2-step approach which involves (i) to estimate the gold standard, and (ii) to access the probability of rejection the null hypothesis. The Monte Carlo simulation was used to evaluate the sensitivity of McNemar's test (type I error rate) to the parameters of the model: variance of the errors, level of detection limit and cutoff value that defines the health state of the individual. The number of simulations was set to guarantee the stable values for the confidence interval of the parameter estimates. All statistical calculations were done with JAVA computer programming language. The McNemar's test was found to be highly sensitive to parameters of the model especially to the variance of the determination error. The type I error rate was inflated even for the relatively low variance of the measurement error. The McNemar's test applied to the concordance analysis of medical diagnosis rejects the true null hypothesis with high rate as the result of the presence of the determination error. The proposed approach leads to alternative validation of agreement problem and provides less biased results.