

ASSESSMENT OF THE DIAGNOSTIC TESTS BY GEE AND LATENT CLASS MODELING

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Lack of diagnostic tests with demonstrably high sensitivity and specificity prevents a more complete understanding of the prevalence and natural history of *Helicobacter Pylori* infection. Beside when a perfect gold standard test does not exist for comparison this become even more complicated. In diagnostic medicine, we are usually concerned with such question as 1-) could the new test replace the established standard test for diagnosis of HP and 2-) if not, could it be used supplementary to established standard tests? For the first question there are many approaches taken to assess the accuracy of a new diagnostic test. The list includes using single imperfect standard, discrepant resolution, composite reference standard among many. In the absence of a gold standard, in recent years Latent Class Analysis is proposed to evaluate the accuracy of a new test to replace the standard tests with patients characteristics included as covariates. In another modeling approach 'GEE approaches to marginal regression models for diagnostic tests are proposed for evaluation of the value of a new test as a supplement to the standard tests with the patients characteristics also included as covariates. In this work the accuracy of a new test called 'direct enzyme immunoassay (HpSA) 'which only uses stool samples in HP diagnosis will first be evaluated by a latent class analysis approach and secondly by GEE approach including age, gender and the outcome of HP treatment as covariates when exist it will be assessed as a supplementary to such other tests as histological examination, rapid urea test, PCR test, IgG and Igm antibodies measured both in adult and/or children. Issues encountered in both modeling approaches will be addressed.