Performance of enzyme immunoassay and PCR for rapid diagnosis of *Helicobacter pylori* infection

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Abstract

Helicobacter pylori infection in humans is one of the most widespread infeetions today, and its eure prevents peptie uleer recurrence. Various methods are available for detecting H. pylori, but all have limitations. During recent years, noninvasive diagnostic tests have gained in significance. This work aims to assess the performance of//, pylori antigen monoclonal enzyme immunoassay (EIA) and PCR for diagnosis of H. pylori infection in comparison with the standard methods (culture and histology). The study included 80 selected patients, who underwent upper endoscopy for evaluation of dyspeptic symptoms. During each endoscopic procedure, multiple biopsy specimens were obtained from the antrum for culture, histology and PCR analysis. Stool samples were collected from all patients for detection of H. pylori antigen by monoclonal EIA. In 38 (47.5%) of the patients' biopsy specimens, H. pylori was identified, of which 16 (20%) yielded positive results by culture and histology, 10 (12.5%) i)y culture only and 12 (15%) by histology only. No H. pylori was detected in the remaining 42 (52.5%) gastric tissue specimens. PCR amplification yielded positive results in 30 out of 38 patients with H. pylori infection as determined by the standard methods and negative results in 50 patients. The sensitivity and specificity of PCR were 78.9% and 100٩/٥ respectively while the positive and negative predictive values were 100% and 84% respectively. By EIA, 36 out of 38 patients infected with H. pylori yielded positive results and 41 out of 42 non infected patients showed negative results. The sensitivity and specificity of EIA were 94.7% and 97.6®/o respectively while the positive and negative predictive values were 97.3% and 95.3% respectively. In conclusion, despite of the reduced sensitivity of PCR as a rapid diagnostic tool, it was at least as sensitive as culture for primary detection of H. pylori infection. In addition, it was concluded that monoclonal EIA, as a new rapid non-invasive diagnostic tool showed excellent perfor- mance with a high overall sensitivity and specificity as well as its logistical ease of use. Further studies are recommended to assess the performance of the monoclonal EIA as a diagnostic tool in children and as a lon**g-term** follow-up of patients after medical treatment.

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