

## **A Diagnostic Accuracy Study: Comparison of Two Different Molecular-Based Tests (GenoType HelicoDR and Seeplex Clar-H. pylori ACE Detection), in the Diagnosis of Helicobacter pylori Infections**

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**Abstract :** Aim: The aim of this study was to compare diagnostic values of two different molecular-based tests (GenoType® HelicoDR ve Seeplex® H. pylori-ClaR- ACE Detection) in detection presence of the H. pylori from gastric biopsy specimens. In addition to this also was aimed to determine resistance ratios of H. pylori strains against to clarytromycine and quinolone isolated from gastric biopsy material cultures by using both the genotypic (GenoType® HelicoDR, Seeplex ® H. pylori -ClaR- ACE Detection) and phenotypic (gradient strip, E-test) methods. Material and methods: A total of 266 patients who admitted to Konya Education and Research Hospital Department of Gastroenterology with dyspeptic complaints, between January 2011-June 2013, were included in the study. Microbiological and histopathological examinations of biopsy specimens taken from antrum and corpus regions were performed. The presence of H. pylori in all the biopsy samples was investigated by five differnt dignostic methods together: culture (C) (Portagerm pylori-PORT PYL, Pylori agar-PYL, GENbox microaer, bioMerieux, France), histology (H) (Giemsa, Hematoxylin and Eosin staining), rapid urease test (RUT) (CLOtest, Cimberly-Clark, USA), and two different molecular tests; GenoType® HelicoDR, Hain, Germany, based on DNA strip assay, and Seeplex ® H. pylori -ClaR- ACE Detection, Seegene, South Korea, based on multiplex PCR. Antimicrobial resistance of H. pylori isolates against clarithromycin and levofloxacin was determined by GenoType® HelicoDR, Seeplex ® H. pylori -ClaR- ACE Detection, and gradient strip (E-test, bioMerieux, France) methods. Culture positivity alone or positivities of both histology and RUT together was accepted as the gold standard for H. pylori positivity. Sensitivity and specificity rates of two molecular methods used in the study were calculated by taking the two gold standards previously mentioned. Results: A total of 266 patients between 16-83 years old who 144 (54.1 %) were female, 122 (45.9 %) were male were included in the study. 144 patients were found as culture positive, and 157 were H and RUT were positive together. 179 patients were found as positive with GenoType® HelicoDR and Seeplex ® H. pylori -ClaR- ACE Detection together. Sensitivity and specificity rates of studied five different methods were found as follows: C were 80.9 % and 84.4 %, H + RUT were 88.2 % and 75.4 %, GenoType® HelicoDR were 100 % and 71.3 %, and Seeplex ® H. pylori -ClaR- ACE Detection were, 100 % and 71.3 %. A strong correlation was found between C and H+RUT, C and GenoType® HelicoDR, and C and Seeplex ® H. pylori -ClaR- ACE Detection (r:0.644 and p:0.000, r:0.757 and p:0.000, r:0.757 and p:0.000, respectively). Of all the isolated 144 H. pylori strains 24 (16.6 %) were detected as resistant to claritromycine, and 18 (12.5 %) were levofloxacin. Genotypic claritromycine resistance was detected only in 15 cases with GenoType® HelicoDR, and 6 cases with Seeplex ® H. pylori -ClaR- ACE Detection. Conclusion: In our study, it was concluded that; GenoType® HelicoDR and Seeplex ® H. pylori -ClaR- ACE Detection was found as the most sensitive diagnostic methods when comparing all the investigated other ones (C, H, and RUT).

**Keywords :** Helicobacter pylori, GenoType® HelicoDR, Seeplex ® H. pylori -ClaR- ACE Detection, antimicrobial resistance

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