PROSPECTIVE VALIDATION OF ENDOFASTER FOR A REAL-TIME DIAGNOSIS OF H. PYLORI INFECTION DURING UPPER ENDOSCOPY

Abstract Submitted

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INTRODUCTION: Endofaster is a new technology based on a real-time analysis of the gastric juice that can provide informations regarding Hp infection and pH value of the gastric contents. In a previous pilot study, the potential accuracy of EndoFaster in diagnosing H. pylori infection during upper GI-endoscopy has been shown.

AIMS & METHODS: Aim of this prospective study was to validate the efficacy of EndoFaster in a cohort of patients undergoing upper GI-endoscopy. Consecutive >45 year old patients undergoing upper GI-endoscopy without PPI or antibiotic therapies in the previous 4 weeks were enrolled. EndoFaster is an innovative device that is interposed between the endoscope and the suction system. After aspiration of 5-10 ml of gastric juice, EndoFaster performs an automatic analysis of the ammonium concentration of gastric juice within 2 minutes. Based on the previous pilot study, the test was considered positive for H. pylori infection when the ammonium concentration was >65 ppm/ml and negative when <55 ppm/ml, being indeterminate in the 55-65 ppm/ml interval. Histology with the addition of urea breath testing in discordant cases was considered as the reference standard for assessing H. pylori infection.

RESULTS: Overall, 114 patients were included in the study. However, 13 (11.4%; mean age: 63 years) were excluded, because the aspirated gastric juice was insufficient for determining ammonium concentration. In the remaining 101 patients (mean age: 57 years; male: 42%), H. pylori infection was present in 41 (41%) patients at reference standard. The test with EndoFaster resulted to be positive in 43 (43%), negative in 47 (46%), and indeterminate in 11 (11%) cases, respectively. When excluding the patients with an indeterminate result, sensitivity, specificity, PPV and NPV of EndoFaster for H. pylori infection resulted to be 97.4%/88.5%/86,0%/97,9%, respectively.

CONCLUSION: In this validation study, EndoFaster showed an overall feasibility of 76% for a real-time determination of H. pylori status. The test appeared to confirm the high accuracy for H. pylori shown in the previous pilot study.

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