UEGW 2012 - Abstract

THE VALIDATION OF PEPTEST A NEW NON-INVASIVE TECHNOLOGY FOR THE DIAGNOSIS OF LARYNGOPHARANGEAL REFLUX (LPR)

S. Bor [1,*], D. S. Capanoglu [1], E. Yildirim [1], R. Vardar [1], A. Woodcock [2], P. W. Dettmar [2]
[1]Gastroenterology Department, Ege University, izmir, Turkey, [2]RD Biomed Limited, Kingston upon Hull, United Kingdom

INTRODUCTION: Different diagnostic tests are used including 24 hour intraesophageal impedance/pH in diagnosing gastroesophageal reflux disease (GERD). However, pharyngolaryngeal reflux is mostly dependent on the laryngeal examination by an ENT specialist and is still a subjective diagnostic method.

AIMS&METHODS: The study was designed to validate the reliability of a non-invasive lateral flow device (LFD) Peptest™ for pepsin determination following reflux symptoms during intraesophageal impedance measurement (MII-pH).
Twenty patients (age≥18) with Gastroesophageal reflux disease symptoms (heartburn and/or regurgitation once a week or more) who had been referred for multichannel intraluminal impedance-pHmonitoring (MII-pH) were included into the study. Patients with esophageal motility disorders; malignancy, and previous upper GI surgery were excluded. All patients were asked to stop acid suppressive medications 10 days before the measurement. The impedance signals were recorded at the portable recording system (Orion, MMS Inc., The Netherlands) and the hardware was connected to the computer for online evaluation.
Patients were asked to cough and spit into a collection tube 5 minutes after they had a reflux symptom or a reflux attack recorded by the MII online. Saliva samples were preserved in 0.01M citric acid solution until testing. An *in-vitro* Lateral Flow Device LFD (Peptest™) embedded with two unique monoclonal antibodies that can attach to human pepsin (pepsin3) was used for the diagnosis.

RESULTS: The total number of saliva samples analysed for pepsin was 45 from 20 patients (16 male) during intraesophageal impedance measurement. At least one positive pepsin (Peptest™) result was seen in 16 of the patients (80%).
Pepsin was present in 27 samples taken during 40 reflux symptom episodes. The sensitivity of the Peptest™ was shown to be 69%, 4 of 5 patients tested positive by Peptest™ even though they had no reflux as recorded by impedance but the patients did report reflux symptoms.

CONCLUSION: The sensitivity of Peptest™ was shown to be 69% compared to 89% sensitivity for impedance. An interesting observation is that Peptest™ appears to positively correlate with reflux symptoms when no impedance measurement is observed. Further investigation of this phenomenon is required.
The results demonstrate that if a patient presents with reflux like symptoms Peptest™ is likely to objectively identify reflux and as a first line diagnosis excludes the need for an expensive and invasive test procedure in the majority of patients.

Keywords: gastroesophageal reflux disease, pepsin, peptest, pharyngolaryngeal reflux