

DETECTION OF PEPSIN BY IMMUNOASSAY IN PATIENTS WITH LPR AND GERD

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ABSTRACT

Purpose: To provide proof of concept for the use of a non-invasive, sensitive, enzyme-linked immunosorbent assay (ELISA) for human pepsin used as a “spit-in-a-cup” diagnostic for reflux disease.

Study Design: Prospective controlled study.

Methods: Three patient study groups and controls. Controls: 20 adult volunteers with no prior history of laryngopharyngeal reflux (LPR) or gastroesophageal reflux disease (GERD). Controls were asked to expectorate a single random sputum/saliva sample for pepsin ELISA. Group I: 72 subjects with pH-documented untreated LPR; single random expectorated sample. Group II: 20 similar LPR subjects who provided two expectorated samples, before bedtime and upon rising in the morning. Group III: 36 GERD patients with biopsy-proven esophagitis (without LPR symptoms), a single random expectorated sample.

Summary of Results: Fifteen percent (3/20) of the normal control subjects had pepsin detected; although two of those were positive at threshold pepsin levels (~3 ng/mL); the third had silent GERD and Barrett’s esophagitis, diagnosed by subsequent pH testing and esophagoscopy. Pepsin was detected in the expectorated samples of 70% (50/72) of Group I LPR; 95% (19/20) of Group II LPR; and 64% (22/35) of Group III GERD.

Conclusions: Pepsin detection in airway secretions/spit appears to be a sensitive and specific, non-invasive diagnostic for LPR and GERD. The threshold for detection in airway secretions is ~3 ng/mL. The best diagnostic yield for LPR (95%) was seen with double (AM and PM) spit sampling. With a single sample, LPR and GERD patients were pepsin positive 70% and 64%, respectively.

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Key words: Laryngopharyngeal reflux, gastroesophageal reflux, LPR, GERD, pepsin, esophagitis, saliva testing, immunoassay, ELISA, Barrett’s esophagus, esophagitis

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