

Detection of pepsin using a non-invasive lateral flow test for the diagnosis of extra-oesophageal reflux - results of a pilot study

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Introduction: Diagnosis of extra-oesophageal reflux (EOR) remains difficult. 24hr pHmetry or impedance monitoring are invasive and insufficiently sensitive enough for use in EOR and the laryngoscopic signs of EOR can be non-specific. An objective, non-invasive test for the presence of EOR is warranted.

Aims & Methods: We present data from a multi-centre pilot study to establish whether a non-invasive in vitro test was capable of distinguishing between reflux patients and normal controls by detection of the presence of pepsin in sputum/saliva. The study obtained ethical approval and subjects gave written informed consent. Subjects were recruited based on their score of the validated reflux symptom index (RSI)¹. Controls - RSI 0-3 with no heartburn symptoms. Patients - RSI 20+ with visual evidence of reflux on laryngoscopy. Subjects were asked to provide a sample of throat contents by coughing up and spitting into a collection vessel. Patients were also asked to provide a sample at home when they were experiencing symptoms. Samples were tested for the presence of pepsin using a lateral flow test (sensitive down to 3ng pepsin) and sandwich ELISA (sensitive to 2ng/ml) incorporating two unique monoclonal antibodies to human pepsin.

Results: 32 subjects were recruited. 15 control subjects [7M8F, mean (SD) age 43.2(19)yrs; RSI of 0.9(1)]. 16/17 sputum samples obtained from control patients were negative for pepsin. 17 patient subjects [11M6F, mean (SD) age 56.2(16)yrs (p=0.0472 c.f control); RSI of 28.5(5) (p<0.001 c.f. control)]. All provided a sample in clinic of which 35% were positive for pepsin. 11 patients returned a second sample when symptomatic of which 82% were positive for pepsin. At least one positive sample was seen in 71% of patients compared to only 7% in controls (p=0.0003 Fisher's exact test). All samples were tested by sensitive ELISA and agreement was found in 91% of samples.

Conclusion: The results from this pilot study show that pepsin, as a marker for reflux, can be detected in sputum/saliva obtained non-invasively from patients using a novel lateral flow test. 93% of control patients were found not to have pepsin in their sample. 82% of symptomatic patients suspected of having EOR were found to have pepsin in their sample giving clear objective evidence for the presence of reflux in the larynx, pharynx or upper airways. Providing a sample when the patient was symptomatic was shown to improve the diagnostic yield of the test compared to collection in clinic.

Reference(S): ¹Belafsky et al (2002) J Voice 16:274