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## **PEPSIN IN SALIVA AND GASTROESOPHAGEAL REFLUX MONITORING IN 100 HEALTHY ASYMPTOMATIC SUBJECTS AND 65 PATIENTS WITH SIGNIFICANT HEARTBURN/REGURGITATION**

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### **INTRODUCTION/OBJECTIVES:**

Pepsin is a protease originating from pepsinogen secreted into gastric juice from chief cells, found only in the stomach. Its presence in the oesophagus or more proximally suggests gastro-oesophageal reflux (GOR). Several studies have measured pepsin in saliva to determine its value as marker of GOR. Patients with clinically significant heartburn may have GORD, hypersensitive oesophagus or functional heartburn.

### **AIMS & METHODS:**

The aim of this study was to measure pepsin in saliva with objective assessment of GOR by impedance-pH (MII-pH) in a cohort of asymptomatic subjects and consecutive patients with clinically significant heartburn (according to the Montreal definition of GORD).

100 healthy subjects, age 30.7 y (range 19-55) and 65 pts with +ve Reflux Disease Questionnaire (RDQ) score, age 49.7y (range 25-71) underwent MII-pH monitoring and simultaneous saliva sampling. Subjects collected expectorated saliva on waking, one hour after lunch and dinner. Pepsin was detected using a lateral flow test with two unique monoclonal antibodies to pepsin (Peptest™, RDBiomed Ltd). The cut off value to determine pepsin positivity was 25ng/ml. Pts were divided into 3 phenotypes based on MII-pH results. 1) GORD (increased oesophageal acid exposure time (AET) (10.4 % ± 1.4) and SAP +ve, n=26). 2) Hypersensitive oesophagus (HO)(normal AET and SAP +ve, n=18) and 3) Functional Heartburn (FH)(normal AET and SAP -ve for acid/non-acid reflux, n=12).

### **RESULTS:**

All healthy subjects selected had normal MII-pH testing. 36/100 normal subjects had at least 1 sample +ve (20% had 1 sample +ve, 12% had 2 samples +ve and 4% had 3 samples +ve). In pepsin +ve samples, the median (25%>75%) pepsin conc. was 118 (64-181)ng/ml. In GORD patients, 21/26 had at least 1 sample +ve (3 patients had 3 samples +ve) and pepsin conc. was 152 (72-250)ng/ml. In HO patients 15/18 had at least 1 sample +ve (4 had 3 samples +ve) and pepsin conc. was 250(74-250)ng/ml. In contrast, only 2/12 FH patients had at least 1 sample +ve and pepsin conc. was 76(67-85)ng/ml. Considering the ability to identify patients with heartburn related to reflux (GORD + HO) Peptest had a sensitivity of 95%, specificity 89%, PPV 97% but a NPV of 57%.

### **CONCLUSION:**

Pepsin was found in the saliva of a proportion of healthy individuals with no reflux symptoms. Pepsin is significantly more likely to be detected in patients with heartburn related to reflux (SAP +ve) i.e. GORD and HO, (and in higher conc.) than in normal subjects or patients with functional heartburn.