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OPTIMISATION OF THE PEPTEST DIAGNOSTIC TEST FOR DETECTION OF GORD USING PEPSIN AS A MARKER: AN IDEAL PRIMARY CARE TOOL.

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Introduction: The diagnostic test Peptest™ detects pepsin, which is exclusively produced by the stomach, in expectorated saliva and is a quick and easy unique marker of the reflux of gastric contents responsible for gastro-oesophageal reflux disease (GORD)¹.

A study into the ability of Peptest to detect patients with GORD was performed. The optimal sampling strategy to give the highest diagnostic yield was investigated.

Method: Patients attending routine endoscopy clinic at Rotherham General Hospital with symptoms of GORD with erosive oesophagitis (EO) or if the score of the GERDQ² was ≥ 8 . The patients provided 1-10 saliva samples with randomised strategies that were blindly analysed for the presence of pepsin using Peptest™ and concⁿ of pepsin determined (≥ 16 ng/ml).

Results: 59 GORD subjects (30M:27F; mean age 57; 83% on PPI) provided 283 expectorated saliva samples of which 149 samples (53%) were Peptest positive representing 47 GORD subjects with at least 1 Peptest positive sample (80%) [significantly greater than a control group¹ 38 %, $p < 0.0001$ Fisher's exact test].

Pepsin concⁿ ranged from 0-500ng/ml with median 30ng/ml (IQR 0-164) and mean 94ng/ml (SD 133) [significantly greater than a control group¹ $p < 0.0001$, Mann Whitney U test].

There were 22 patients with EO, 35 patients with non-erosive reflux disease (NERD) and 2 patients with Barrett's Oesophagus (BO) with at least 1 sample pepsin positive: 68% for EO (mean 68ng/ml), 86% for NERD (mean 105ng/ml) and 100% (mean 152ng/ml) for BO.

Peptest results based on timing of the sample is given in Table 1.

Table 1: The breakdown of Peptest results in GORD patients by sample timing.

Time	number samples	mean pepsin conc ⁿ ng/ml	% samples positive
All	283	94	53%
On first waking	37	55	38%
Symptomatic	57	111	60%
0-120 min PP	108	116	60%
0 min PP	18	108	56%
5-55 min PP	14	143	71%
60 min PP	43	151	70%
65-115 min PP	24	78	42%
120 min PP	9	29	44%

Conclusion: Optimal sampling time for diagnosis of GORD by Peptest is 60 minutes after a meal or within 15 minutes of a symptomatic episode. The ease of the test allows for saliva samples to be taken before commencing treatment, but even amongst pre-treated EO patients (where gastroscopy is often negative) Peptest can still recognise the underlying reflux. Peptest, therefore, has the potential to be used as the first line investigation in patients suspected of reflux. Those

without 'alarm' symptoms and who test 'positive' could therefore be managed in general practice. Referral for gastroscopy or for other invasive investigations can be reserved for those for whom there is separate need (e.g. to check BO, if reflux symptoms are refractory, or for opportunistic cancer screening).

References: 1. Hayat JO et al (2015). *Gut* 64:373-380

2. Jones R et al (2009). *APT* 30(10):1030-1038

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