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Title: Assessment of the potential of a novel detection method for measuring pepsin as a biomarker of reflux

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Introduction: Clinical assessment of gastric reflux occurrence (by intraluminal impedance or pHmetry) is well-validated. However, such measurements techniques are invasive and time-consuming. They may also not allow for assessment of extra-oesophageal reflux by aerosolisation or microaspiration. Pepsin is a proteolytic enzyme secreted by the stomach.

Objective: To validate a rapid non-invasive system for the detection of reflux.

Aim: To compare measured pepsin in saliva using a novel lateral flow device to a previously described ELISA methodology.

Methods: Ethical approval was granted for this study by Sheffield Hallam University SBS Ethics Committee. Thirty archived saliva samples (provided by 5 free-living individuals) were assessed for pepsin content by the novel lateral flow device (PeptestTM) and a previously described ELISA methodology.

Results: There was a significant correlation between the two methodologies ($P < 0.0001$, Spearman $r = 0.7353$). A total of 12 of the 30 samples had levels of pepsin that were detectable by the pepsin ELISA but not by PeptestTM, including three samples with pepsin values higher than 20 ng/ml. Bland-Altman Ratio Plots suggest that the pepsin ELISA methodology tends to predict a higher concentration of pepsin in the samples than the PeptestTM on average but that overall there was no bias between the two test procedures (Bias ELISA: PeptestTM = 1.448 with 95% limits of agreement from -1.152 to 4.048). Exclusion of the samples that were negative by Peptest (but not the pepsin ELISA) leaves a total of 18 paired datasets which still showed a significant non-parametric correlation ($P = 0.0084$, Spearman $r = 0.6008$).

Conclusions: The PeptestTM methodology had higher minimum detection limits than the pepsin ELISA. However, as thePeptestTM procedure takes approximately 20 minutes to analyse a sample with minimal training required, it may represent a useful tool to aid preliminary diagnosis of reflux.

Author Keywords: Pepsin, reflux, saliva, free-living, Peptest