

oesophageal acid exposure time (AET) or temporal association of reflux events with patient symptoms. Several key issues required for reflux-symptom association, such as the most appropriate pH threshold and time window, have not been defined and current statistical analysis has important limitations: Symptom Index (SI) is a measure of an effect size, not of confidence. Symptom Association Probability (SAP) is a measure of confidence but not of size and applies the Fisher exact test inappropriately (dividing time into fixed intervals does not produce independent counts).

This study presents a systematic assessment of symptom association in ambulatory gastro-oesophageal reflux monitoring data.

**Methods** Acid reflux (pH) and symptom data were acquired by wireless pH recording (Bravo, Given Imaging). 163 consecutive patients presenting with predominantly typical reflux symptoms (heartburn, regurgitation) studied 2006–2009 with duration >3.7 days were studied (636 days). Data were exported in XML format, and analyzed by custom written program. A systematic analysis was performed.

**Results** (1) Symptom markers A finite-state algorithm was developed to equalise patient responses, removing redundant markers in one pass with reflux detection. (2) pH threshold: Setting pH thresholds for reflux detection is not physiological and a weighted S-shaped ('dose response') curve could be more appropriate. This was assessed varying the centre and steepness of the curve to maximise association with SI and SAP. A steep S-curve almost indistinguishable to a threshold was found: maximum correlation SI pH threshold 4.5, correlation 0.55; SAP pH threshold 4.4, correlation 0.34. (3) time window: The frequency of reflux associated symptom markers was above baseline only during minute 1. The association in minute 2 was no higher than chance. (4) Over time (day 1–4) SI was stable; however SAP increased progressively. Both parameters increased with the frequency of reflux events. CI for SI were computed by assuming a binomial distribution (Agresti-Coull method).

**Conclusion** A novel approach to symptom association of ambulatory reflux monitoring data is presented. Confounding due to redundant symptom markers is removed by a finite-state algorithm. Acid threshold of pH 4.5 and a time window of 1 min provided optimal correlation with SI. Computing SI with CI provides a statistically valid, single parameter that describes both size of effect and likelihood of association between reflux events and symptoms.

**Competing interests** M. Fox Grant/Research Support from: Given imaging, R. Sweis: None Declared, A. Anggiansah: None Declared, T. Wong: None Declared, D. Menne: None Declared.

**Keywords** pH monitoring, Reflux, symptom association probability, symptom index.

PWE-066

### SYMPTOM ASSOCIATION IN AMBULATORY GASTRO-OESOPHAGEAL REFLUX MONITORING: A SYSTEMATIC ANALYSIS

doi:10.1136/gut.2011.239301.329

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**Introduction** The diagnosis of gastro-oesophageal reflux disease (GORD) by ambulatory reflux monitoring is based on