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.

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

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

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