An Acoustic Device and Associated Method to Monitor the Functions of Sphincters in the Gastrointestinal (GI) Tract

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Background
Researchers at the University of Calgary have developed a minimally invasive acoustic device and associated method for ambulatory monitoring of sphincters in the GI tract. This device can directly and quantitatively measure the levels of the opening and closing of the sphincters.

Human GI tract consists of seven sphincters, ring like muscle fibers that control the passage of content from one specialized portion of the GI tract to another. Malfunction of GI sphincters results in a variety of disorders and diseases such as Gastro-Esophageal Reflux Disease (GERD), which is one of the most common disorders, affecting an estimated seven percent of the adult population. GERD results from malfunction of the lower esophageal sphincter (LES), which no longer prevents the contents of the stomach from refluxing into the esophagus resulting in various esophageal symptoms, mucosal damage and potentially a precursor to esophageal cancer.

Existing methods for diagnosing GERD use upper GI Endoscopy, Esophageal pH monitoring, ambulatory multichannel intraluminal impedance pH monitoring, etc. Most of these methods provide indirect ways to assess gastroesophageal reflux, but fail to provide any direct measurement of the opening and closing of the Lower Esophageal Sphincter (LES) that cause it.

The present invention introduces a novel method that uses an oscillator (sound generating device) and a pair of microphones attached to a tiny catheter. One of the microphones is positioned in the vicinity of one end of the LES and the oscillator is positioned close to the other end of the sphincter. The microphone detects signals produced by the oscillator and a signal processing method is used to detect and analyze changes in characteristics of sound signals augmented from sphincter’s opening and closing. A second microphone can be positioned in mid-esophagus to detect non-LES related artifacts, which can be utilized by an adaptive filter to improve signal quality.
Area of Application
- GERD diagnostic device
- Sphincter monitoring in the GI tract
- Diagnostic of other esophageal motility disorders, including achalasia, gastroesophageal junction obstruction, esophageal spasm, nutcracker esophagus and hypertensive lower esophageal sphincter, etc.
- Assessment of pyloric function, including pyloric stenosis or weakness

Competitive Advantages
- Direct and accurate detection of opening and closing GI sphincter levels
- Allows long-term (24-48 hours) direct ambulatory monitoring
- Can be standalone test for GI motility and as complementary to ambulatory esophageal pH, impedance and/or manometry monitoring of the LES
- Can monitor the motility dynamics of the pylorus (the gastro-duodenal sphincter)
- Inexpensive and low cost manufacturing

Stage of Development
- 2nd generation prototype
- Laboratory testing on a LES motility dynamics model - completed
- Chronic validation studies on animals and humans - underway

Intellectual Property Status
- Patent filed

Publications: