Remote-controlled capsule endoscope safely examines the stomach

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A study from researchers in Germany showed that magnetic maneuvering of a modified capsule endoscope in the stomach of healthy volunteers under clinical conditions is safe, well-tolerated, and technically feasible. Maneuverability of the capsule within the stomach was excellent and visualization of the gastric mucosa, the inner lining of the stomach, was satisfactory in the majority of subjects. Apart from a single experiment performed with a supervising flexible gastroscope, this was the first study to use the system in the stomach of healthy subjects. The study appears in the January issue of *GIE: Gastrointestinal Endoscopy*, the monthly peer-reviewed scientific journal of the American Society for Gastrointestinal Endoscopy (ASGE).

Data from prospective studies indicate that gastric cancer screening programs may have a positive impact on mortality associated with the disease. Upper endoscopy is the reference method for the detection of gastric mucosal alterations (changes in the lining of the stomach) and therefore might be the most appropriate screening tool. Unfortunately, some view endoscopy as uncomfortable, and worry about low patient compliance. Capsule endoscopy might offer a more "patient-friendly" alternative. However, conventional capsule endoscopies have shown that visualization of the stomach is highly variable.

A conventional capsule endoscope examines the small intestine using a pill-sized video capsule which has its own lens and light source. The camera takes 50,000-60,000 digital images during the procedure. The system consists of an ingestible pill camera (26 x 11 mm), a data

recorder, and computer software for interpretation. Images recorded by the capsule camera are transmitted and stored on a data recorder worn by the patient. The images are downloaded onto a computer, where they are then viewed and interpreted by a specially trained gastroenterologist. A wireless colon capsule for visualizing the colon for screening purposes has been developed, but is not currently FDA approved for use in the U.S.

"To address the problems with a conventional capsule endoscope in visualizing the stomach, a new tool for maneuvering the capsule using an external handheld magnet was developed, allowing targeted investigation of all regions of the stomach," said study lead author Junta Keller, MD, Department of Internal Medicine, University of Hamburg, Hamburg, Germany. "The aim of our study was to evaluate the safety and feasibility of the magnetic maneuvering of a capsule endoscope in a human stomach. We found that the magnetic maneuvering of the capsule was safe and very well-tolerated, with excellent responsiveness of the capsule to movements of the outer magnet so that detailed visualization of the gastric mucosa could be achieved."

Methods

The objective of the study was to assess the safety and efficacy of the manipulation of a modified capsule endoscope with magnetic materials in the human stomach by using a handheld external magnet. Ten healthy volunteers (five men and five women) in an open clinical trial at the Israelitic Hospital in Hamburg, Germany, participated in the study. The magnetic maneuverable capsule (MMC) is a modification of a standard colon capsule with magnetic disks inserted inside one of the domes of the capsule. The MMC is activated by a novel radiofrequency switch (replacing the thermal switch previously used to initiate MMCs) and operates at four frames per second from a single camera. It transmits images to the data recorder via a set of sensors placed on the patient's

skin. These can be viewed in real time by using the Real Time Viewer and compiled after the examination into a video by using the RAPID workstation. The external magnet paddle has a single strong magnet.

The study participants swallowed the MMC and sherbet powder to distend the stomach, which flattens the folds of the stomach. The external magnetic paddle was used to manipulate the MMC within the stomach. MMC responsiveness was evaluated on a screen showing the MMC film in real time. The main outcome measurements were safety and tolerability, time the MMC remained in the stomach, its responsiveness to the magnetic paddle, and the area of the stomach lining visualized.

Results

The MMC was always clearly attracted by the magnetic paddle and responded to its movements. In seven participants, maneuverability was graded as excellent because the MMC followed the rotating and tilting movements of the magnetic paddle smoothly. It remained in the stomach for approximately 39 minutes (plus or minus 24 minutes). In seven subjects, both the cardia (part of the stomach immediately adjacent to the esophagus) and the pylorus (part of the stomach through which contents are emptied into the small intestine) were inspected and 75 percent or more of the gastric mucosa was visualized (greater than or equal to 50 percent in all of the remaining subjects). The researchers noted that a learning curve was clearly recognizable (identification of MMC localization, intended movements). Some limitations of the study included small amounts of fluid that blocked the view of an area of the stomach called the fundus and gastric distention was not sufficient to flatten all gastric folds. There were no adverse events.

Study participants completed a questionnaire after the procedure, asking about difficulties swallowing, pain or other complaints. Nine participants

reported no complaints and one reported mild complaints of feeling pressure. The researchers concluded that remote control of the MMC in the stomach of healthy volunteers using a handheld magnet is safe and feasible. Responsiveness of the MMC was excellent, and visualization of the stomach lining was good, although not complete, in the majority of subjects. The system appeared to be clinically valuable and should be developed further.

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