Magnetic-anchor-guided endoscopic submucosal dissection shows promise for gastric cancer

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A prospective clinical trial from researchers in Japan shows magnetic-anchor-guided endoscopic submucosal dissection for large early gastric cancer to be a feasible and safe method in humans. Endoscopic submucosal dissection (ESD) is useful in the en bloc removal (in a single large piece) of large gastric lesions because it reduces the risk of a local recurrence caused by removing the lesions piecemeal (in multiple small pieces). ESD is a complicated procedure that requires a high level of skill by the endoscopist. The magnetic-anchor-guided endoscopic submucosal dissection (MAG-ESD) technique was developed to facilitate the standard ESD procedure. The researchers note that to their knowledge, this is the first clinical trial to use MAG-ESD for early gastric cancer in humans. 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).

Endoscopy is a procedure that uses an endoscope -- a thin, flexible tube with a light and a lens on the end to look into the esophagus, stomach, duodenum, small intestine, colon, or rectum, in order to diagnose or treat a condition. There are many types of endoscopy, including colonoscopy, sigmoidoscopy, gastroscopy, enteroscopy, and esophogogastroduodenoscopy (EGD). Endoscopy allows direct visualization of the inner most lining of the gastrointestinal tract. This inner lining is called the mucosa. Many cancers originate from the mucosa of the gastrointestinal tract. Some examples include colon,

esophageal and gastric (stomach) cancer.

Precancerous changes and early stage cancers can be removed through an endoscope provided the cancer has not spread beyond the surface layers of the gastrointestinal lining. An important technique in removing these lesions is endoscopic mucosal resection (EMR). In this technique, a needle is passed through the endoscope and a liquid solution is injected under the area of interest, in effect "lifting" the abnormal tissue and separating it from the deeper intestinal layers. The abnormal lesion is then removed ("resected") with a snare; the tissue is subsequently retrieved through the endoscope and examined under a microscope.

ESD is a specific EMR technique where a lesion, generally larger than what can be removed by standard EMR, is separated from the deeper layers of the intestinal wall under direct vision of the endoscopist. The endoscopist utilizes an electrocautery device to dissect the lesion (overlying the device) from the deeper intestinal layers (below the device). Unlike conventional surgery, where structures in the abdomen are readily able to be shifted (retracted) allowing better visualization, there is no good method to provide retraction when using the endoscope in ESD. MAG-ESD, controlled by an extracorporeal electromagnet, facilitates the standard ESD procedure by providing this retraction capability using magnets.

According to the researchers, the MAG-ESD technique allowed for excellent visualization of the submucosal layer because it made suitable tissue tension possible. This simplifies a gastric ESD, even for large lesions in the gastric body. The study showed that the long-term exposure to the magnetic field did not cause any unwanted physiological or mental effects. Furthermore, no delayed complications or allergies related to the stainless steel magnetic anchor were observed. All the tumors were resected en bloc, without any perforation or severe uncontrollable bleeding.

Patients and Methods

The purpose of this prospective single center clinical trial was to evaluate the feasibility of MAG-ESD for large early gastric cancer in humans. The technique had previously been reported as successful in a porcine model. Twenty-five patients, median age 70 years, with early gastric cancer measuring > 20 mm located in the gastric body (stomach) were seen on an inpatient basis for an ESD at the National Cancer Center Hospital in Tokyo, Japan. The final aim was to achieve an en bloc resection (removal of the entire cancerous growth).

The MAG system is composed of both internal and external components. The intracorporeal magnetic anchor consists of a hand-made stainless steel magnetic weight of six grams, and microforceps connected by a short thread. The magnetic anchor is delivered into the stomach of the patient through a hollow tube (overtube) that incorporates the endoscope and the magnetic weight. The extracorporeal magnetic control system includes a 35 cm extracorporeal magnet whose movement is controlled by the up-down motion of the external magnet itself as well as a movable examination table. The mobile examination table enabled control of the internal magnetic anchor so as to achieve ideal mucosal lifting to allow for the gastric submucosal dissection.

The procedure began in standard ESD fashion with the injection of a liquid cushion into the submucosa and initial entry into the submucosa with the electrocautery device. The procedure was then carried out using the new MAG-ESD technique. The magnetic anchor was clipped to the free edge of the lesion in the stomach which can now be controlled by the large magnet outside the patient to provide an appropriate amount of tension. This makes it possible to peel back the portion of the lesion now separated from the submucosa, clearing the view of the endoscopist for safer removal of the lesion. After endoscopic resection, both the resected tissue and the magnetic anchor(s) were removed from the

stomach.

The demographic and clinical features of each patient were recorded in a case report form. Two gastrointestinal endoscopists assessed the data as to whether the magnetic anchor facilitated a gastric ESD, and was classified either "supportive" or "not supportive." The en bloc resection rate, complications, total operation time, bleeding, perforation and recurrence rate were also evaluated.

Results

The MAG-ESD technique was utilized in 25 patients. All tumors were resected en bloc (median size 5.5 cm), without any perforations or uncontrollable bleeding. All magnetic anchors were safely removed. The MAG system was evaluated as helpful in facilitation ESD in 23 of the 25 patients. In 21 patients, only one magnetic anchor was needed to achieve the desired result, either by rotating the patient or by moving the examination table. The MAG system effectively facilitated an ESD for all nine tumors located on the greater curvature of the gastric body.

None of the patients experienced physiological or mental abnormalities as a result of magnetic field exposure either during the procedure itself or over the follow-up interval. No delayed adverse effects nor allergies were observed because of the stainless steel of the magnetic anchor. Eight weeks after an MAG-ESD, all artificial defects caused by ESD were completely healed. Neither recurrent cancer nor distant metastases were observed in any of the patients during follow-up.

The study authors noted that the electromagnetic control system was cumbersome and advised that the system should be miniaturized to allow wider clinical application. While this human clinical trial demonstrated MAG-ESD's feasibility and safety, and offered excellent visualization due to suitable tissue tension, the researchers advised that further

innovations are warranted to apply the MAG procedure in daily clinical practice.

Source: American Society for Gastrointestinal Endoscopy