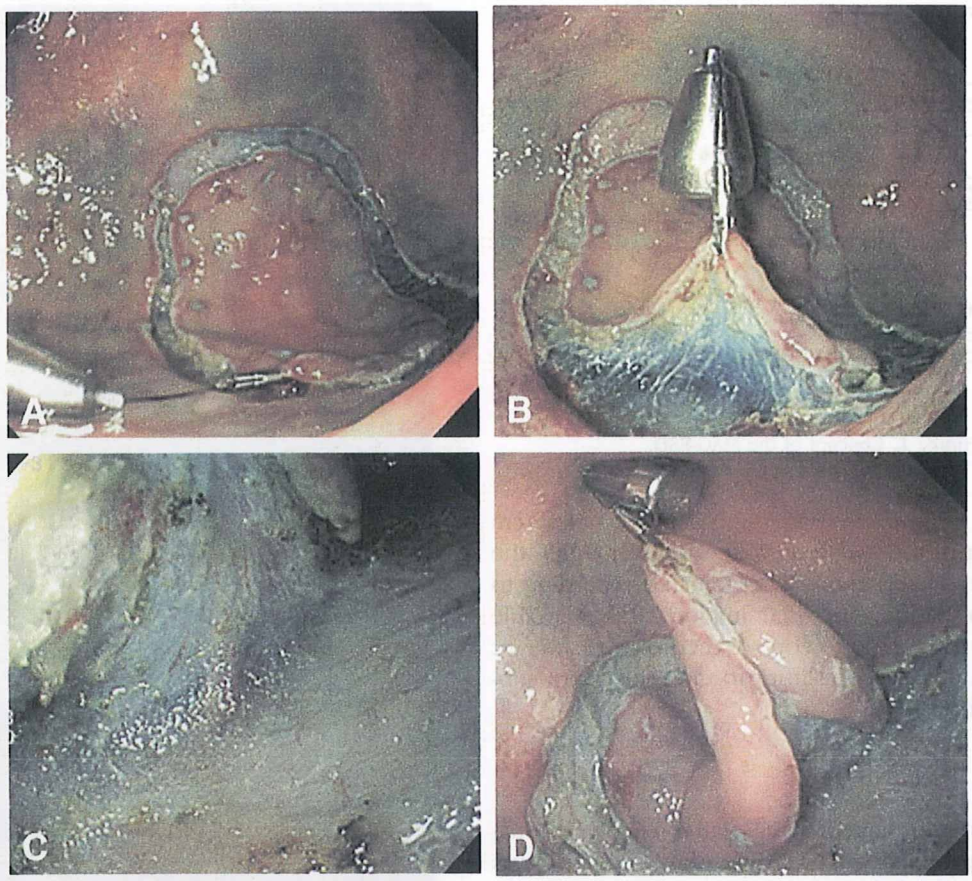

Figure 3. Magnetic-anchor–assisted ESD for large EGC. **A,** Fitting the magnetic anchor onto the tip of the gastric mucosa before applying the magnetic force. **B,** Lifting of the gastric tissue and stretched submucosal layer under strong counter-traction by the magnetic anchor. **C,** Good visualization of vessel in submucosal layer under counter-traction by magnetic force. **D,** Controllable traction by the magnetic anchor with a magnetic field.

RESULTS

The MAG-ESD technique was performed in 25 patients (M/F, 17/8; median age 70 years, range 48-85 years; median tumor size, 30 mm, range 20-70 mm).

The results of the MAG-ESDs are shown in Table 1. All tumors were resected en bloc, without any perforations or severe uncontrollable bleeding. The median size of resected specimen was 55 mm (33-125 mm). The median procedure time was 80 minutes (50-240 minutes). One resection was histologically confirmed as being noncurative because of deep submucosal invasion with positive vertical margins and lymphatic-vessel involvement. This patient underwent additional radical surgery.

One magnetic anchor was required in 21 cases, and 2 magnetic anchors were used in 4 cases. All magnetic anchors were safely retrieved. Two endoscopists assessed that the MAG system was supportive in 23 patients. In particular, the MAG system effectively facilitated an ESD for all 9 tumors located on the greater curvature of the gastric body. However, the magnetic anchor was not helpful in 2 patients. In one case, it was difficult to inflate the gastric lumen because of air leakage through the hiatus hernia.

TABLE 1. Results of 25 patients treated by MAG-ESD

En bloc resection rate	25/25 (100%)
Median resection size (mm)	55 (range 33-125)
Complications	0/25 (0%)
Median time consumption (min)	80 (range 50-240)
Exposure time for magnetic field (min)	30 (range 10-110)
Endoscopist's assessment	
Supportive	23
Not supportive	2

In another case, it was impossible to pull the gastric tissue toward the proper direction, even after changing the patient's position.

None of the patients experienced physiologic and mental abnormalities as a result of long-term magnetic-field exposure, neither before nor after the procedure. After a mean of 30 minutes (range 10–110 minutes) of exposure

to the magnetic field, no adverse effects of standard ESD procedure were observed regarding pulmonary and cardiac function. During a median follow-up of 20 months (range 15–32 months), neither 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 cured. Neither recurrent cancer nor distant metastases were observed in any of the patients during follow-up.

DISCUSSION

The present study is, to our knowledge, the first clinical trial by using MAG-ESD for EGC in human beings. The feasibility of the technique for gastric cancer treatment was already evaluated in an animal study. The MAG-ESD technique permits excellent visualization of the submucosal layer, because it is possible to achieve suitable tissue tension. This simplifies a gastric ESD, even for large lesions located in the gastric body. The long-term exposure to the magnetic field did not cause any unwanted physiologic or mental effects. Furthermore, no delayed complications or allergies related to the stainless steel of the magnetic anchor were observed. All the tumors were resected en bloc, without any perforation or severe uncontrollable bleeding.

Endoscopic resection is comparable in many respects to conventional surgery, with the advantages of being less invasive and more cost efficient.[15,16] Endoscopic removal of cancer was initially attempted by using colorectal polypectomy with a high-frequency electric surgical cautery.[17] The use of endoscopic polypectomy to treat pedunculated or semipedunculated EGC was first described in 1974 in Japan. In 1984, the technique of EMR, the so-called strip biopsy, was devised for endoscopic snare polypectomy.[18] Today, EMR is established and widely accepted as a minimally invasive treatment for EGC.[19] Although several techniques have been reported to make EMR procedures easier and safer,[20,21] these cannot be used to remove, en bloc, lesions larger than 2 cm in diameter.[22,23] Piecemeal resection may cause the pathologist to inadequately stage the specimen. Furthermore, there is a high risk of a recurrence after a piecemeal resection.[24,25]

An ESD is superior to a standard EMR and provides en bloc specimens with a standard single-channel gastroscope. After an endoscopic resection, pathologic assessment of depth of cancer invasion, degree of cancer differentiation, and lymphatic or blood-vessel involvement allows an accurate prediction of the risk of lymph-node metastasis.[26] The risk of developing lymph-node or distant metastasis is then weighed against the risk of surgery.[27-29]

Endoscopic resection should be safe, effective, and applicable to a wide variety of clinical situations. However, an ESD still requires an experienced endoscopist with a high level of skill, especially when using a single working-channel gastroscope. Recently, the technique of percutaneous traction-assisted EMR by using a laparoscopic port to create a strong counter-traction was reported.[30-32] However, all previous trials showed that the technique was complicated, invasive, and did not make ESD easier.

Magnets and magnetic fields were used to direct the catheter tip during catheter procedures.[33] A magnetic anchoring system was used to achieve laparoscopic surgery by using a single trocar.[34] Very recently, the feasibility of using magnetically anchored instruments was reported as a promising technique to facilitate natural orifice transluminal endoscopic surgery in a porcine model.[35] These magnets may also provide a way to alter tissue contours without any direct contact. A direct-current–generated magnetic field, as used in magnetic resonance imaging, is regarded as the least invasive or even the most appropriate noninvasive procedure that can be medically applied.

In 21 of our patients, only one magnetic anchor was needed to achieve the desired result, either by rotating the patient or by moving the examination table. In 4 cases, 2 magnetic anchors were required. In 2 cases, a second magnetic anchor was helpful. With the other 2 cases, however, the second anchor did not help, because the MAG system did not provide adequate visualization for submucosal dissection or allow suitable maneuvering of the endoscopic devices. This was caused by underinflation of the gastric cavity. Therefore, to obtain better visualization during an MAG-ESD, the prevention of air leakage because of a hiatus hernia should be achieved.

Another limitation of this procedure was that the extracorporeal electromagnetic control system is too large and cumbersome. Although it was possible to achieve hands-free fixation of the mucosa by using the magnetic anchor tractioned with the extracorporeal electromagnet, the system should be miniaturized to allow wider clinical application.

In conclusion, this prospective clinical trial proved that MAG-ESD can feasibly be used in human beings. The MAG-ESD technique was able to obtain excellent visualization by suitable tissue tension and to facilitate the procedures. Further innovations are warranted to apply the MAG procedure in daily clinical practice.

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