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A possible endoscopic therapy for large hiatal hernia complicated with refractory gastroesophageal reflux disease

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A hiatal hernia (HH) is usually associated with gastroesophageal reflux disease (GERD). An HH can increase the incidence of GERD.[1] The coexistence of these diseases increases the difficulty of treatment and can be challenging for endoscopic treatment. Therapeutic methods for small HHs (≤2 cm) combined with refractory GERD have recently been emerging. However, there are still knowledge gaps in the endoscopic treatment of large HHs (≥3 cm) combined with refractory GERD. We developed a new endoscopic method called hiatal hernia-endoscopic submucosal dissection (HH-ESD) and performed the present study to clarify the efficacy and safety of HH-ESD.

This clinical trial was approved by the Ethics Committee of the Affiliated People's Hospital of Inner Mongolia Medical University (No. KY201801) and registered at the China Clinical Trial Registry (clinical trial number: ChiCTR2000034032). The inclusion criteria were (1) an age of 18 to 75 years; (2) symptoms of acid regurgitation and heartburn that were not significantly relieved or that relapsed after >2 months of daily proton pump inhibitor (PPI) therapy; (3) diagnosis of a sliding HH (≥3 cm) by gastroscopy, radiography, and esophageal manometry before the procedure; and (4) 24 h pH monitoring results in accordance with a DeMeester score of >30.0.[2] The exclusion criteria were (1) a history of surgery around the gastroesophageal junction (GEJ) that destroyed the normal anatomical structure and (2) any esophageal motility disorders affecting esophageal contractile function. All patients provided informed consent. In total, 14 patients underwent HH-ESD at the Affiliated Hospital of Inner Mongolia Medical University and Affiliated People's Hospital of Inner Mongolia Medical University from December 2018 to December 2019. All operations were performed by one experienced endoscopist (HQ Hu).

All patients underwent assessment using the Gastroesophageal Reflux Disease-Health-Related Quality of Life scale, Gastroesophageal Reflux Disease Questionnaire, gastroscopy (Los Angeles classification was used to grade the severity of esophagitis), upper gastrointestinal radiography, 24 h pH monitoring, esophageal manometry, and gastroesophageal radionuclide imaging. All examinations were repeated at the 6-month post-operative follow-up visit.

The procedure was performed as follows [Figure 1]. When the patient was awake, routine gastroscopy was performed to observe any esophageal mucosal lesions, the looseness of the cardia, and the size of the HH. The HH removal range was then marked by electrocoagulation. After induction of general anesthesia, methylene blue was submucosally injected 0.5 cm outside the mark to elevate the lesion away from the muscle layer; this injection was repeated three to five times. A circumferential incision was then performed using a Golden knife from Micro-Tech (Nanjing) Co., Ltd (Jiangsu, China). Next, during submucosal dissection, 1/2 to 2/3 of the mucosa of the circumference of the GEJ and hernia sac were removed to prevent post-operative stenosis. The actual extent of resection depended on the size of the hernia sac and the severity of the mucosal lesions. The wound was observed for submucosal hemorrhage and deep damage, and exposed blood vessels on the wound were treated with argon plasma coagulation or hemostatic forceps. Finally, the specimen was collected, its length and width were measured, its resection area was calculated, and it was sent out for pathologic examination. The operative procedure is shown in the Supplementary Video [http://links.lww.com/CM9/A817].

After HH-ESD, PPIs and mucosal protective agents were taken orally from day 3 to week 4 postoperatively.

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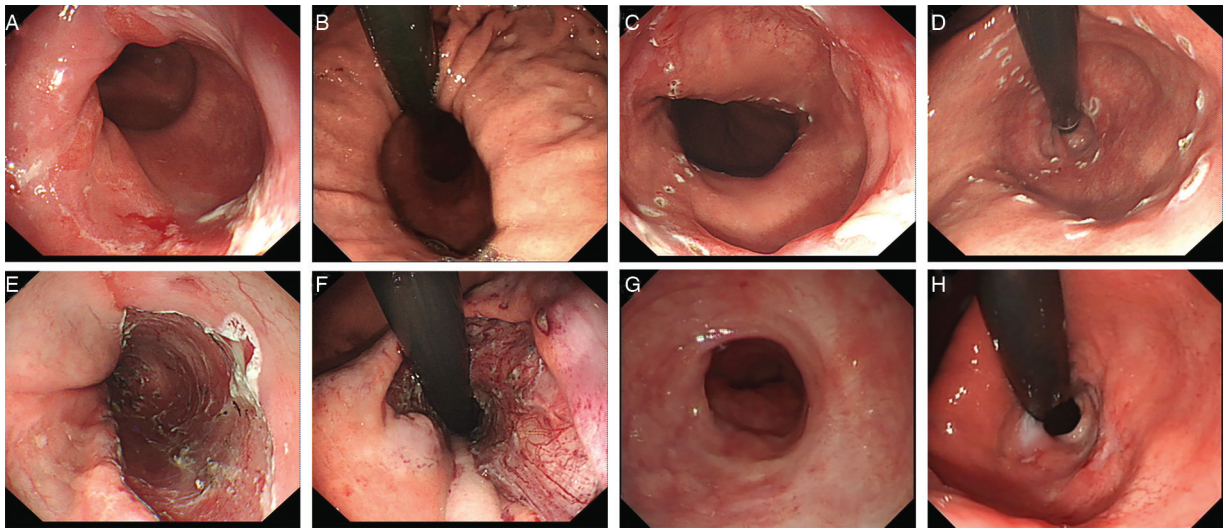

Figure 1: HH-ESD procedure and post-operative follow-up. (A) Mucosal erosion at the GEJ. (B) The endoscope was flipped to observe a large sliding HH. (C) Electrocoagulation mark in forward view. (D) Electrocoagulation mark in retroflexed view. (E) Submucosal dissection in forward view. (F) Submucosal peeling in retroflexed view. (G) Six months after the operation, the scar had healed well and the surface mucosa was smooth. (H) The cardia had tightened, the hernia sac had shrunk, and the anti-regurgitation valve had formed 6 months after the operation. GEJ: Gastroesophageal junction; HH: Hiatal hernia; HH-ESD: Hiatal hernia (HH)-endoscopic submucosal dissection.

Statistical analysis was performed using SPSS 22.0 (IBM Corp, Armonk, NY, USA). The Wilcoxon signed-rank test was used for evaluation of continuous variables. A *P* value of <0.05 was considered statistically significant.

All 14 patients successfully underwent HH-ESD. Their baseline characteristics are summarized in Supplementary Table 1 [http://links.lww.com/CM9/A816]. Six months after HH-ESD, all relevant evaluation indices were significantly improved with the exception of the gastroesophageal reflux index (GERI) [Supplementary Table 2, http://links.lww.com/CM9/A816]. The GERI decreased in 4/5 of the patients, although the decrease was not statistically significant; this was considered to be related to the small sample size. Gastroscopy showed that the severity of esophagitis improved in all 14 patients (100%), and Los Angeles grade A/B/C/D was present in 1/6/7/0 patients before treatment and in 6/0/2/0 patients after treatment; the remaining six patients showed no manifestations of esophagitis. The gastroscopy results six months after HH-ESD are shown in Figure 1G and H. Radiography showed smooth passage of barium in all patients and no stenosis or obstruction was observed in any of the patients.

No intra-operative adverse events occurred. After HH-ESD, delayed hemorrhage occurred in one patient (7.1%) and dysphagia occurred in seven patients (50.0%); in six of these seven patients, the dysphagia was spontaneously resolved without any treatment within 3 months. Twelve patients (85.7%) stopped using PPIs completely 6 months later.

Dysphagia is a major complication after treatment of HHs. Fortunately, none of the patients required surgery or dilatation. The four main causes of dysphagia can be summarized as follows: (1) Development of dysphagia may be related to the normal healing of local tissues. (2) Dysphagia may also be related to the scope of resection. In our study, "crescentic resection" was performed in 13 patients; that is, 1/2 to 2/3 of the mucosas of the circumference of the GEJ and hernia sac were removed. All patients who underwent crescentic resection showed good therapeutic effects, and six patients had mild dysphagia that improved spontaneously. Only one patient who had severe reflux lesions and a sliding HH with a paraesophageal hernia was treated by circumferential resection. The resection area was 30 cm^2. The patient developed severe dysphagia that lasted for >6 months post-operatively. Therefore, we consider that circumferential resection may significantly increase the incidence of stenosis and that the presence of a paraesophageal hernia may greatly weaken the therapeutic effect of HH-ESD. (3) Dysphagia may also be related to reflux stimulation. After treatment, patients should take oral PPIs for 4 weeks, and are advised to maintain good living habits. (4) Finally, we cannot rule out the presence of differences in individual responses to HH-ESD. The contractile function of the esophagus and the constitution of scars will also affect the therapeutic outcome.

Endoscopic treatment of GERD is being constantly updated, and anti-reflux mucosectomy (ARMS) has attracted our attention.[3-5] The mechanism of both HH-ESD and ARMS is the same. However, the two procedures are different in three respects: (1) The indications are different. ARMS is used to treat refractory GERD with a small HH ($\leq$2 cm), whereas HH-ESD is used to treat a large HH ($\geq$3 cm) in patients with refractory GERD. (2) The excision techniques are different. ARMS mostly uses endoscopic mucosal resection, whereas HH-ESD uses endoscopic submucosal dissection. (3) The excision area is different. The excision areas vary during ARMS; that is, clinicians may remove 1/2 to 4/5 of the mucosa of the circumference of the GEJ. HH-ESD involves removal of not only the mucosa around the GEJ but also part of the mucosa of the hernia sac; that is, 1/2 to 2/3 of the mucosa of the circumference of the GEJ and hernia sac are removed.

The main limitation of this technique is that an experienced endoscopist is needed for performance of all procedures; thus, the learning curve may be a potential limiting factor. Compared with endoscopic mucosal resection and radiofrequency ablation, HH-ESD is difficult and time-consuming. In this study, we conducted a preliminary exploration of HH-ESD. Verification of the therapeutic effect of HH- ESD still requires further data and long-term follow-up.

In conclusion, HH-ESD is a possible endoscopic treatment for large HHs with refractory GERD. It is safe and feasible with promising short-term results.

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Conflicts of interest

None.

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