ORIGINAL ARTICLE: Clinical Endoscopy

EUS-guided FNA biopsy of the muscularis propria of the antrum in patients with gastroparesis is feasible and safe

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Background and Aims: EUS-guided FNA biopsies of the muscularis propria of the gastric wall in patients with gastroparesis could replace the routine use of surgical full-thickness biopsies for assessing the loss of the interstitial cells of Cajal (ICCs) and cellular infiltrates in the myenteric plexus. We investigated the efficacy and safety of EUS-guided FNA biopsies of the muscularis propria of the gastric antrum in gastroparesis and compared the tissue with a surgically obtained full-thickness biopsy specimen in the same patient.

Methods: This was a prospective, nonrandomized, feasibility trial. Patients with gastroparesis who were undergoing gastric neurostimulator placement were enrolled. Patients had a gastric wall measurement by radial EUS in the body and antrum of the stomach followed by linear EUS examination and FNA of the muscularis propria in the antrum by using a 19-gauge core needle. Within 24 hours, a full-thickness biopsy specimen of the antrum was obtained surgically during neurostimulator placement. Endoscopic and surgical specimens were compared for tissue morphology, number of ICCs (c-kit stain) and enteric neurons (S-100 stain), and fibrosis (trichome) for each patient. The correlation coefficient of the ICC count per high-power field was used to compare both specimens. Continuous data were compared by using a t test.

Results: Eleven patients (10 female, 1 male), with a mean age of 40.6 years, were enrolled in the trial. EUS-guided core biopsies were successful in obtaining sufficient tissue for the histologic assessment of ICCs in 9 patients (81%) and for the myenteric plexus in 6 patients (54%). There was a good correlation coefficient (0.65) when both surgical and endoscopic groups were compared for the loss of ICCs. Mild serosal bruising and/or localized hematoma formations were noted at the sites of EUS biopsies, but there were no serosal tears, perforations, or adverse effects on the hospitalization and outcomes.

Conclusions: EUS-guided FNA of the gastric muscularis propria in patients with gastroparesis is safe and provides adequate tissue for full histologic assessment. (Clinical trial registration number: NCT01916460.) (Gastrointest Endosc 2016;83:327-33.)

Gastroparesis is a chronic disorder of gastric motility characterized by delayed gastric emptying of solids without evidence of mechanical obstruction. Gastroparesis presents with early satiety, postprandial fullness, nausea, vomiting,

Abbreviations: EUS-FNA, EUS-guided FNA; H&E, bematoxylin and eosin; HPFs, bigb power fields; ICC, interstitial cells of Cajal; IRB, institutional review board.

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and abdominal discomfort. In severe cases, gastroparesis can significantly diminish quality of life because of chronic nausea and vomiting, malnutrition, and multiple hospital admissions. ¹⁻³ Diabetes and idiopathic etiologies represent

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the two major causes of gastroparesis. A Recent data indicate several structural changes associated with gastroparesis. Loss of interstitial cells of Cajal (ICCs) and decreased number of enteric neurons as well as increased number of immune infiltrates in the myenteric plexus of the muscularis propria were seen in patients with gastroparesis who underwent full-thickness gastric body biopsy. The addition to the loss of ICCs, studies suggest that there is an accompanying loss of the expression of neuronal nitric oxide in enteric neurons in animal models of gastroparesis.

The utility of echoendoscopy in examining the structural changes of the gastric wall in patients with gastroparesis has not been reported previously. Core biopsy of the gastric wall by using a linear echoendoscope and a 19-gauge needle was feasible in patients with gastric wall thickening. The primary aims of our study were (1) to investigate the efficacy and safety of EUS-guided FNA (EUS-FNA) biopsies of the muscularis propria of the antrum in patients with gastroparesis and to compare the tissue obtained endoscopically to a surgically obtained full-thickness biopsy in the same patient and (2) to map the total wall thickness as well as specifically measure smooth muscle dimensions in the gastric body and antrum of patients with gastroparesis.

BACKGROUND

EUS can visualize the 5 layers of the gastric wall that correlate with specific histology. The first 2 layers are the superficial and deep mucosa, the third layer is the submucosa, the fourth hypoechoic layer represents the muscularis propria, and the fifth hyperechoic layer represents the serosa. 10 ICCs can be seen on a histologic specimen of the fourth layer (muscularis propria). Echoendoscopes and endoscopic miniprobes have various frequencies (5-20 MHz). Although high-frequency miniprobes can better visualize the GI wall, their use is hampered with the loss of acoustic coupling and the need for constant water instillation to achieve better visualization of the GI lumen. 11 Radial and linear echoendoscopes have been used for years in assessing gastric wall thickness for different pathologies, with high accuracy. 12 Although radial and linear echoendoscopes involve low frequencies (5-10 MHz), the acoustic coupling between the probe and the stomach wall is obtained by placing a water-filled balloon on the tip of the echoendoscope, resulting in clear, stable images of the gastric wall. In addition, the linear echoendoscope provides an opportunity to obtain core biopsy specimens of the gastric wall.

METHODS

Study design

This was a prospective, nonrandomized, pilot trial. The study was approved by the Institutional Review Board (IRB) of Texas Tech University Health Science Center on March 3, 2013. The study was registered at Clinicaltrial.gov under this identifier number: NCT01916460. The study was funded by a seed grant from the Paul L. Foster School of Medicine at Texas Tech University Health Science Center. The authors and the coauthors of this study had access to the study data and approved the final version of this manuscript. Inclusion criteria included patients (aged 18-80 years) with objective evidence of gastroparesis who were undergoing gastric neurostimulator placement because they had failed all standard and/or research treatment approaches to control their symptoms. Subjective evidence of gastroparesis included the following: documented symptoms of gastroparesis for >6 months, >7 episodes of vomiting per week, refractoriness, or intolerance to antiemetics and prokinetic medications. Objective evidence was supported by the documentation of delayed gastric emptying of solid meals (>60% gastric retention at 2 hours and >10% at 4 hours postprandial) by using a 4-hour scintigraphic method with a standard egg booster meal. Exclusion criteria were documented organic or intestinal pseudoobstruction, primary eating or swallowing disorders, rumination syndrome, psychogenic vomiting, cyclic vomiting syndrome, systemic sclerosis, thyroid and adrenal disease, psychiatric diagnosis of chemical dependency, cancer, peritoneal dialysis, and pregnancy. In addition, patients with a history of gastric surgery such as partial gastric resection, vagotomy, or bariatric procedures were excluded.

Technique

After careful reading and discussion, each patient gave written, informed consent. Demographics and clinically relevant data were obtained along with the results of a 4-hour gastric emptying test, EGD results, *Helicobacter pylori* status, and basic laboratory tests (Hb A_{1c}, blood cell counts, and coagulation parameter). The clinical evaluation of gastroparesis symptoms was through the PAGI-SYM standard questionnaire.

Patients with gastroparesis who met the criteria for enrollment in the study had been evaluated by a gastroenterologist (R.W.M.), and they were scheduled to undergo gastric neurostimulator placement. On the morning of the planned surgery, they underwent radial and linear EUS examination of the stomach wall as per IRB protocol. A radial Olympus GF-UE160-AL5 echoendoscope (Olympus America Inc, Center Valley, Pa) was used to measure the total wall thickness and muscularis propria thickness of the body, antrum, and pylorus by using harmonic echo. The tip of the echoendoscope was covered with a balloon; balloon distension with water was used to improve the visualization of the gastric wall by the echoendoscope. The 5 layers of the gastric wall were visualized, and the measurement of the total wall thickness and the thickness of the fourth layer (muscularis propria) was obtained (Fig. 1) Three measurements were obtained from each site. After that, the linear EUS was used to obtain a core biopsy specimen of the stomach wall in the antrum with a 19-gauge core biopsy needle under

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