GASTRO-HEP News

By Samantha Alleman

US Food and Drug Administration Clears Duodenoscope With Disposable Distal Cap

On September 20, 2017, the US Food and Drug Administration (FDA) cleared the first duodenoscope with a disposable distal cap (Pentax ED34-i10T, Pentax Medical) for the visualization, diagnosis, and treatment of bile duct disorders and various upper gastrointestinal complications. The disposable distal cap is intended to lower the risk of infections by improving access for cleaning and reprocessing.

The FDA issued a Safety Communication in January 2017 regarding an earlier model of the duodenoscope (ED-3490TK, Pentax Medical), in which a design flaw allowed fluids and tissue to enter the device.

No Difference in Quality of Life Between Surgical Procedures for Chronic Pancreatitis

There is no difference in the long-term quality of life following partial pancreatoduodenectomy vs duodenum-preserving pancreatic head resection (DPPHR) for chronic pancreatitis, according to results of a multicenter trial published in the September 2017 issue of *The Lancet*.

Between September 2009 and September 2013, Dr Markus K. Diener and colleagues enrolled 250 patients with chronic pancreatitis in a randomized, controlled, double-blind, parallel-group, superiority trial across 18 hospitals in Europe. The patients, who were scheduled for elective surgical treatment, were evenly split between the 2 procedures. The primary endpoint was mean quality of life within 2 years following the surgical procedure, determined by the European Organisation for Research and Treatment of Cancer QLQ-C30 questionnaire. Patients who underwent partial pancreatoduodenectomy or DPPHR as assigned (111/125 patients and 115/125 patients, respectively) were included in the primary analysis; all 226 patients who received surgical treatment were included in the safety analysis.

Overall, no difference in the quality of life was reported between the 2 groups within 2 years postprocedure (P=.284). Additionally, there was no difference in the incidence and severity of serious adverse events; 52% of patients (61/117) in the partial pancreatoduodenectomy group and 64% of patients (70/109) in the DPPHR group experienced at least 1 serious adverse event. The most common serious adverse events were gastrointestinal problems, reoperations for reasons beyond chronic pancreatitis, and other surgical morbidity.

Laparoscopic Antireflux Surgery Associated With High Recurrence Rate of Gastroesophageal Reflux Disease

Primary laparoscopic antireflux surgery was linked to a high recurrence rate of gastroesophageal reflux disease (GERD) requiring long-term medication or a second antireflux surgery, according to results of a retrospective cohort study published online on September 12, 2017 ahead of print publication in *JAMA*.

Dr John Maret-Ouda and colleagues enrolled 2655 patients who had previously undergone laparoscopic antireflux surgery for GERD between January 1, 2005 and December 31, 2014 in a nationwide, population-based study in Sweden. The study outcome was the recurrence of GERD, demonstrated by the use of proton pump inhibitors or histamine-2 receptor antagonists for at least 6 months, or the need for repeated antireflux surgery. The authors used multivariable Cox regression to assess risk factors for GERD recurrence.

Patients were followed up for a median of 5.6 years. Nearly 18% of patients (470/2655) experienced recurrence of GERD. Of these, 83.6% of patients (n=393) required long-term medication and 16.4% (n=77) underwent a second antireflux surgery. The main risk factors included comorbidity (22.4% for patients with Charlson comorbidity index score ≥1 vs 15.7% for patients with Charlson comorbidity index score 0; hazard ratio [HR], 1.36; 95% CI, 1.13-1.65), female sex (22.0%; HR, 1.57; 95% CI, 1.29-1.90), and older age (21.8% of patients age 61 years or older vs 13.4% for patients age 45 years or younger; HR, 1.41; 95% CI, 1.10-1.81).

Study limitations include an absence of a control group and a lack of data regarding the use of over-the-counter GERD medications.

Regular Statin Use in Patients With Alcoholic Cirrhosis Linked to Lower Mortality Rates

Regular statin use in patients with alcoholic cirrhosis was associated with lower rates of mortality and decompensation. Results of the retrospective case-cohort analysis were published online on September 7, 2017 ahead of print publication in *Alimentary Pharmacology and Therapeutics*.

Dr Ulrich C. Bang and colleagues identified 24,748 patients with alcoholic cirrhosis based on Danish registry data for 1995 through 2014. Of these, 5417 patients were eligible for propensity-score matching comparing

use and nonuse of statins. The primary outcome was mortality rate.

The prevalence of statin use was 15%. Among patients using statins, the mortality rate was 88 per 1000 years (95% CI, 73-15), compared to 127 per 1000 years (95% CI, 114-141) among nonusers (HR, 0.57; 95% CI, 0.45-0.71). Consistent use of statins was linked to a lower mortality rate, although statin dose and mortality risk were not related.

The authors concluded that controlled clinical trials are needed before statin use in patients with alcoholic cirrhosis can be recommended.

High Rates of Success, Reliability for Vibration-Controlled Transient Elastography in Patients With Nonalcoholic Fatty Liver Disease

Vibration-controlled transient elastography (VCTE) has high rates of success, reliability, and reproducibility for estimating liver stiffness measurement (LSM) and controlled attenuation parameter (CAP) in a multicenter setting, according to results of a study published online on August 31, 2017 ahead of print publication in *Hepatology*. Previous studies on VCTE have reported low success rates in patients with nonalcoholic fatty liver disease (NAFLD).

To assess the performance characteristics of a VCTE device with probes in sizes medium and extra-large (FibroScan 502 Touch, Echosens), Dr Raj Vuppalanchi and colleagues performed 1696 examinations in 992 patients, all of whom had NAFLD confirmed on histology. Concurrent assessments of LSM and CAP were carried out with the VCTE device. A single operator or 2 operators (88% vs 12%, respectively) conducted testing twice in patients. The inability to obtain a valid examination was considered a failure. A limit of agreement greater than 95% between 2 readings indicated a significant disagreement.

In total, 1641 examinations were considered valid. Test results demonstrated a success rate of 96.7% and a reliability rate of 97.6%. The significant disagreement between readings for back-to-back LSM and CAP was 18% and 11%, respectively.

Risk of Postendoscopy Gastrointestinal Bleeding Increased With Warfarin Use

Patients treated with warfarin following an endoscopic procedure had a higher risk of gastrointestinal bleeding than patients receiving direct oral anticoagulants (DOACs), according to results of a nationwide database analysis. Heparin bridging was also associated with an increased risk of bleeding and did not prevent thromboembolism.

For the study, the results of which were published online on September 5, 2017 ahead of print publication in *Gut*, Dr Naoyoshi Nagata and colleagues identified 16,977 patients who underwent high-risk endoscopic procedures and took preoperative warfarin or DOACs from 2014 to 2015. Propensity score-matching was used to compare postprocedure gastrointestinal bleeding and thromboembolism between the 2 treatment groups.

A significantly higher proportion of gastrointestinal bleeding occurred among patients treated with warfarin vs DOACs (12.0% vs 9.9%; *P*=.002). Rates of thromboembolism and in-hospital mortality were similar between the 2 groups (5.4%, warfarin vs 4.7%, DOAC). Patients treated with heparin bridging combined with warfarin or DOAC experienced greater risks of gastrointestinal bleeding than patients treated with DOACs alone. Procedures carrying the highest risk of bleeding were endoscopic injection sclerotherapy, endoscopic mucosal resection, endoscopic submucosal dissection, and endoscopic variceal ligation. Moderate-risk procedures included endoscopic ultrasound–guided fine-needle aspiration and lower polypectomy endoscopic sphincterotomy.

In Brief

Researchers retrospectively evaluating 4903 patients with hepatocellular carcinoma found that a reduced starting dosage of sorafenib (Nexavar, Bayer) was connected to decreased treatment costs, pill burden, and discontinuation owing to adverse events. Reduced dosing was not associated with inferior overall survival compared with standard dosing. *J Clin Oncol*. 2017 Sept 5. Epub ahead of print. doi:10.1200/jco.2017.73.8245.

Results of a systematic review and meta-analysis demonstrated that metal stents were superior to plastic stents for walled-off necrosis resolution and carried lower rates of bleeding events, stent occlusion, and perforation. However, metal stents had higher migration rates compared with plastic stents. *Gastrointest Endosc*. 2017 Aug 31. Epub ahead of print. doi:10.1016/j.gie.2017.08.025.