GASTRO-HEP News

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US Food and Drug Administration Approves Use of Duodenoscope With Disposable Elevator Component

The US Food and Drug Administration (FDA) approved the use of a duodenoscope with a disposable elevator component (Pentax Medical Video ED34-i10T2, Pentax Medical) to provide access and visualization to the upper gastrointestinal tract to treat bile duct disorders and related conditions, according to a press release published online by the FDA on November 18, 2019. It is the first duodenoscope with a disposable elevator component to receive approval. The FDA previously cleared devices with removable endcap components.

The duodenoscope was reviewed through a 501(k) premarket clearance pathway, which allows device manufacturers to submit evidence to the FDA establishing that the new device is substantially equivalent to a legally marketed predicate device.

On August 29, 2019, the FDA issued a safety communication recommending duodenoscope manufacturers and health care facilities begin transitioning from devices with fixed endcaps to those with disposable components. Disposable designs reduce the number of parts that need to be cleaned and reprocessed between uses, which can lower the risk of contamination.

Risks associated with the use of the duodenoscope include bleeding, burns, electric shock, infection, and perforation.

Rifabutin-Based Treatment for *Helicobacter pylori* Infection Receives FDA Approval

On November 4, 2019, the FDA approved the first rifabutin-based treatment (Talicia, RedHill Biopharma Ltd) for use in adults with *Helicobacter pylori* infection, according to a press release published online by the manufacturer. The treatment, a delayed-release capsule consisting of 10 mg of omeprazole (equivalent to 10.3 mg of omeprazole magnesium), 12.5 mg of rifabutin, and 250 mg of amoxicillin and indicated as a first-line therapy, offers an alternative to metronidazole and clarithromycin, the current standard of care.

Two phase 3 studies of rifabutin use among *H pylori*–positive adults experiencing epigastric pain and/or discomfort demonstrated 90% efficacy in eradication of the condition. Resistance to rifabutin was 0% vs 17% with clarithromycin. This result is consistent with data showing that therapies containing clarithromycin fail in approximately 25% to 40% of patients.

One percent of patients (4/305) in the confirmatory phase 3 trial discontinued treatment with rifabutin owing to an adverse reaction. Adverse reactions resulting in discontinuation included nasal congestion, nasopharyngitis, and nausea and vomiting.

The company expects to launch the treatment in the United States in the first quarter of 2020.

Poor Immunization Status and Screening at Diagnosis in Children With Inflammatory Bowel Disease

Children with inflammatory bowel disease (IBD) often do not receive required vaccinations at diagnosis or proper screening before initiation of biologic agents, according to results of a cohort study published online on November 5, 2019 ahead of print publication in *Inflammatory Bowel Diseases*. These study findings highlight a need for updated guidelines for patients in this population.

Dr Massimo Martinelli and colleagues conducted a multicenter, retrospective cohort study of 430 children with IBD across 13 European centers. Patients were divided into 2 groups: those who were diagnosed before June 2012, and those who were diagnosed after. The researchers evaluated and compared vaccination rates at diagnosis, immunization status, screening at biologic or immunosuppressant initiation, and reasons for incomplete immunization.

Vaccination rates at diagnosis were considered unsatisfactory for rotavirus (1.9%); papillomavirus (5.9%); chickenpox (18.4%); pneumococcus (18.6%); meningococcus C (23.5%); *Haemophilus influenzae* (81.9%); and measles, mumps, and rubella (89.3%). Only 38 patients (8.8%) had received complete immunization. Among the patients with incomplete immunization, specific vaccinations were recommended for 79 patients (18.4%). No differences were noted between the 2 groups. At the start of biologic therapy, 92.1% of patients were screened for latent tuberculosis, with as many as 9 different screening strategies and several inconsistencies. At immunosuppressant initiation, 22% of patients were tested for Epstein-Barr virus (EBV) status, whereas 96.2% of EBV-naive patients were treated with azathioprine, with no differences between groups 1 and 2. Reasons for incomplete immunization included need for immediate immunosuppressive therapies (27.8%), parental refusal (7.7%), and cost (1.6%).