

FDA Mandates Black Box Warning of HBV Infection Risk for 2 Leukemia Therapies

Although labeling for both ofatumumab (Arzerra, Glaxo-SmithKline) and rituximab (Rituxan, Genentech/Biogen Idec) carries a warning about the risk of reactivation of hepatitis B virus (HBV) infection, cases of reactivation continue to occur, and some of these recurrences have resulted in patient death. Because of this, the warning about the association between the agent and HBV infection recurrence will be presented as a Black Box warning in the labeling.

The US Food and Drug Administration (FDA) is recommending that physicians who administer ofatumumab or rituximab therapy screen patients for HBV infection before initiating therapy and that they monitor patients who have a history of HBV infection for signs of reactivation. Patients should be monitored not only during therapy but also for several months after therapy has been discontinued, according to the FDA.

Ofatumumab is indicated for the treatment of chronic lymphocytic leukemia (CLL), and rituximab is indicated for the treatment of CLL, non-Hodgkin lymphoma, and rheumatoid arthritis. Both agents are immunosuppressants.

Fecal Microbiota Pill Prevents *Clostridium difficile* Infection Recurrence

A 100% cure rate was achieved in 27 patients with recurrent *Clostridium difficile* infection who took tablet-sized pills containing a concentrate of fecal bacteria. The patients all had had at least 4 bouts of *C difficile* infection and ingested between 24 and 36 capsules containing fecal bacteria that was, in most instances, donated by family members. This finding was reported by a team from the University of Calgary, Alberta at IDWeek 2013, which took place on October 2 to 6 in San Francisco, California.

The donated feces was reduced to a bacterial concentrate that was then encapsulated in tri-layered gelatin capsules to ensure prevention of pill leakage or degradation before passing through the stomach to the small intestine. The pills were individually constructed. Fecal microbiota transplantation (FMT) has otherwise been achieved via enema colonoscopy or nasogastric tube. Fecal microbiota concentrate in pill form may provide a less invasive and less costly method of delivery, according to the study's lead author Thomas Louie, MD, professor of medicine at the University of Calgary, who decided to study pill use for FMT after administering fecal microbiota in pill form and achieving cure in a patient with recurrent *C difficile* infection who twice failed to respond to the enema method and could not tolerate nasogastric administration.

High Efficacy Rate with Radiofrequency Ablation in Dysplastic Barrett Esophagus Confirmed

Radiofrequency ablation (RFA) is associated with a 91% rate of remission in patients with dysplastic Barrett esophagus, according to Nicholas J. Shaheen, MD, MPH, AGAF, and colleagues from the Center for Esophageal Diseases and Swallowing at the University of North Carolina School of Medicine in Chapel Hill.

To determine trends regarding intestinal metaplasia and esophageal dysplasia in patients with Barrett esophagus, the researchers conducted a systematic review and meta-analysis of studies published in PubMed and EMBASE. They found that, in addition to the high rate of complete eradication of dysplasia, complete eradication of intestinal metaplasia was achieved in 78% of patients; however, recurrence of intestinal metaplasia occurred in 13%, leading the researchers to caution that patients should be closely monitored after completion of therapy. Adverse events (most commonly narrowing of the esophagus, pain, and bleeding) were reported in less than 5% of patients.

The study was reported in the October issue of *Clinical Gastroenterology and Hepatology* and can be accessed for free at [http://cghjournal.org/article/S1542-3565\(13\)00603-4/fulltext](http://cghjournal.org/article/S1542-3565(13)00603-4/fulltext). The researchers intend to follow up this study with analysis of the US RFA Registry. For further information regarding RFA, readers can access the position statement of the American Gastroenterological Association on Barrett esophagus at http://www.gastro.org/practice/medical-position-statements/Barretts_MPS.pdf.

Updated Guidelines on the Management of Acute Pancreatitis Released

Updated guidelines on the management of acute pancreatitis have been published in the September issue of the *American Journal of Gastroenterology* and can be accessed from the website of the American College of Gastroenterology at <http://gi.org/guideline/acute-pancreatitis>. The guidelines include updated recommendations on diagnosis, initial assessment, nutrition, and management. The guidelines emphasize the importance of early aggressive intravenous hydration and the value of endoscopic retrograde cholangiopancreatography (ERCP), particularly in patients with concomitant acute pancreatitis and cholangitis, who should undergo ERCP within 24 hours of hospital admission. A discussion on the updated guidelines, presented by lead author Scott Tenner, MD, MPH, associate professor of medicine at the State University of New York in Brooklyn, is available via podcast at <http://gi.org/physician-resources/podcasts/the-american-journal-of-gastroenterology-author-podcasts>.