GASTRO-HEP News

By Samantha Alleman

US Food and Drug Administration Approves Marketing of Medical Device for Reduction of IBS-Associated Pain in Adolescents

On June 7, 2019, the US Food and Drug Administration (FDA) approved marketing of a medical device (IB-Stim, Innovative Health Solutions) for relief of functional abdominal pain in patients ages 11 to 18 years with irritable bowel syndrome (IBS) when used in conjunction with other IBS therapies.

The prescription-only device consists of a small single-use electrical nerve stimulator that is placed behind the patient's ear. A battery-powered chip emits low-frequency electrical pulses to stimulate nerve bundles in and around the ear continuously for 5 days, after which the chip is replaced. The device can be used for up to 3 consecutive weeks.

The FDA reviewed data from a study of 50 patients (11-18 years old) with IBS who were treated either with the device (n=27) or with a placebo device (n=23). Patients were allowed to continue stable doses of medication to treat chronic abdominal pain. Changes in worst abdominal pain, usual pain, and Pain Frequency Severity Duration (PFSD) scores were measured from baseline to the end of the third week. Baseline worst pain was similar between the 2 groups.

In a repeated measures analysis, the treatment group showed improvement in worst pain every week from baseline. The treatment group also experienced a greater change in composite PFSD scores from baseline to week 3. Fifty-two percent and 59% of patients in the treatment group demonstrated at least a 30% decrease in usual pain and worst pain, respectively, at the end of week 3 compared with 30% and 26% of patients who received the placebo. Patients reported mild ear discomfort (n=6) and adhesive allergy at the site of application (n=3).

Patients with hemophilia, cardiac pacemakers, or a diagnosis of psoriasis vulgaris should not use this device.

Universal Screening for Lynch Syndrome in Elderly Patients With Colorectal Cancer Has Low Diagnostic Yield

The diagnostic yield of universal screening for Lynch syndrome among patients with newly diagnosed colorectal cancer decreased substantially in patients 70 years and older, according to results of a retrospective cohort study published online on June 11, 2019 ahead of print publication in *Annals of Internal Medicine*. Due to very low efficiency, it may be reasonable to stop screening in patients 80 years and older, although more research is needed.

Dr Dan Li and colleagues evaluated 3891 patients with newly diagnosed colorectal cancer who underwent screening for Lynch syndrome between 2011 and 2016. The diagnostic yield of age-restricted screening was compared to that of universal screening using reflex mismatch repair immunohistochemistry of colorectal cancer tumor.

Age-restricted screening identified 58 cases of Lynch syndrome in patients diagnosed with colorectal cancer at or before age 70 years (diagnostic yield, 1.49%), 60 cases in patients diagnosed at or before age 75 years (diagnostic yield, 1.54%), and 62 cases in patients diagnosed at or before age 80 years (diagnostic yield, 1.59%). Universal screening identified 63 cases of Lynch syndrome overall, 5 (7.9%) of which were in patients older than 70 years, and 1 (1.6%) of which was in a patient older than 80 years. Using 75 years as the upper age limit for screening missed 3 out of 63 (4.8%) cases of Lynch syndrome but resulted in 1053 (27.1%) fewer cases requiring tumor mismatch repair immunohistochemistry. Using 80 years as the upper age limit missed 1 out of 63 (1.6%) cases and resulted in 668 (17.2%) fewer cases requiring tumor mismatch repair immunohistochemistry. The number of tumors needed to screen to identify 1 case of Lynch syndrome increased from 20 among patients diagnosed with colorectal cancer by age 50 years to 208 and 668 among patients diagnosed between ages 71 to 80 years and after 80 years, respectively.

Based on these data, the authors concluded that screening patients ages 75 to 80 years is not cost-effective.

In Brief

Fiber supplement company Naturlax offers all-natural, sugar-free psyllium fiber supplements that are derived from fruits, vegetables, and plant extracts. The active ingredient among the more than 80 flavor options is psyllium husk, and the supplements are sweetened with a stevia and erythritol blend. The supplements can be used in both pediatric and adult patient populations.