Blue dye tablet helps identify polyps during colonoscopy

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Ingestion of a blue dye tablet during bowel prep for colonoscopy could be a significant advance in the early detection of colorectal cancer (CRC). When used in conjunction with colonoscopy, the blue dye increased adenoma detection rate (ADR) by nearly 9 percent, according to a study scheduled for presentation at Digestive Disease Week (DDW) 2018.

Study implications

Every year, nearly 137,000 people are diagnosed with CRC, and more than 50,000 people die from the disease. Yet, the disease is largely preventable with regular screening and is treatable with early detection. The challenge is that polyps are not always detected during screening—many polyps are flat or subtle, making them difficult to identify and remove.

"Identification of cancerous and pre-cancerous lesions is of utmost importance to prevent CRC," said Alessandro Repici, MD, professor of gastroenterology and director of endoscopy at Humanitas University Medical School in Milan, Italy, and a primary investigator of the study. "Our study, which used the highest standard of care, allowed gastroenterologists to better detect and remove difficult-to-see polyps, which has great implications for further preventing this disease."

Study design

Researchers studied 1,205 patients scheduled for colonoscopy at 20 centers worldwide, with each patient randomly assigned to one of three groups: patients who received a full dose of the blue dye, oral delayed-release methylene blue, during the normal colonoscopy preparation process; patients who received a placebo during preparation; and a group of patients who received a half dose of the study drug. The third group was not part of the analysis but was included for masking purposes to make it harder for participating physicians to know which patients were in the active group.

Study results

In patients whose preparation included the full 200 mg dose of the oral delayed-release methylene blue, adenomas, or polyps, and carcinomas were found in 56.3 percent of patients. In the placebo group, which utilized the standard of care, adenomas and carcinomas were identified in 47.8 percent. Both groups were screened with the most up-to-date technology available with monitored withdrawal time and blinded second review to avoid execution bias. More flat and small lesions (less than 5 millimeters) were found in patients who used the full dose of the oral delayed-release methylene blue. Additionally, research showed that with the exception of blue feces and urine discoloration, which were expected effects, less than 6 percent of patients experienced mild adverse effects when taking the tablet.

"While utilizing blue dye to increase ADR is not a new concept, the fact that this technology now comes in tablet form is a major advance," Michael B. Wallace, MD, MPH, professor of medicine and director of the Digestive Disease Research Program at Mayo Clinic in Jacksonville, Florida, and a primary investigator on the Phase III trial. "Our research shows the oral delayed-release methylene blue provides gastroenterologists with a new means to improve their ADR with no

additional inconvenience or safety risks to the patient and no supplemental time required to the endoscopist."

Previously, the blue dye had to be mixed by the providers on site, and then sprayed during the colonoscopy, which could be an imprecise, time-consuming and generally localized process. With the development of the tablet form, the majority of the dye releases in the colon in time for highlighting and detecting mucosal lesions during the colonoscopy.

Study investigators added that the use of Methylene Blue MMX or other technologies should never be considered a substitute for good colonoscopy technique.

Colorectal cancer screening saves lives. Colonoscopy is the only screening method that can screen for and prevent colorectal cancer. According to a study published in the *New England Journal of Medicine*, every 1 percent increase in the ADR corresponds to a 3 percent decline in the incidence of CRC and a 5 percent decline in CRC fatalities.

More information: Douglas A. Corley et al. Adenoma Detection Rate and Risk of Colorectal Cancer and Death, *New England Journal of Medicine* (2014). DOI: 10.1056/NEJMoa1309086

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