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American Gastroenterological Association

AGA releases best practice advice on long term PPI use

Gastrointestinal system should weigh the risks and benefits of PPIs when given for common conditions. The long term use of proton pump inhibitors (PPIs) by patients for GERD, Barrett's esophagus and non steroidal anti-inflammatory drug (NSAID) induced bleeding prophylaxis doubled in the U.S. from 1999 to 2012. American Gastroenterological Association (AGA) stated that when PPIs are appropriately prescribed, their benefits are likely to outweigh their risks. They provide best practice advice based on expert opinion and on relevant publications:

- Long term PPI users should not routinely raise their intake of calcium, vitamin B_{12} or magnesium beyond the recommended dietary allowance
- Long term PPI users should not routinely screen or monitor bone mineral density, serum creatinine, magnesium or vitamin B_{12}
- Patients with GERD and acid related complications should take a PPI for short term healing, maintenance of healing and long term symptom control
- Patients at high risk for ulcer related bleeding from NSAIDs should take a PPI, if they continue to take NSAIDs
- The dose of long term PPIs should be periodically re-evaluated so that the lowest effective PPI dose can be prescribed to manage the condition
- Patients with Barrett's esophagus and symptomatic GERD should take a long term PPI
- Asymptomatic patients with Barrett's esophagus should consider a long term PPI
- Long term PPI users should not routinely use probiotics to prevent infection

Reference: *American Gastroenterological Association, April 6, 2017*

FDA approved indications for proton pump inhibitors in pediatric patients

PPIs block the acid producing enzyme system in the stomach wall and prevent acid production in the stomach. Lack of acid in the stomach prevents ulcer formation; promotes healing of existing ulcers in the esophagus, stomach, duodenum and provides symptom relief. Medications in the PPI drug therapy class have been proven safe and effective in children and adolescents for the short term treatment of Gastro Esophageal Reflux Disease (GERD) and Erosive Esophagitis (EE). The FDA approved pediatric age ranges and indications for PPIs are provided in Figure 1.

Omeprazole: The safety and effectiveness of omeprazole have been established in pediatric patients 1 to 17 years of age for the treatment of symptomatic GERD, treatment of EE due to acid mediated GERD and maintenance of healing of EE due to acid mediated GERD. It is also indicated in patients 1 month to less than 1 year of age for the treatment of EE due to acid mediated GERD.

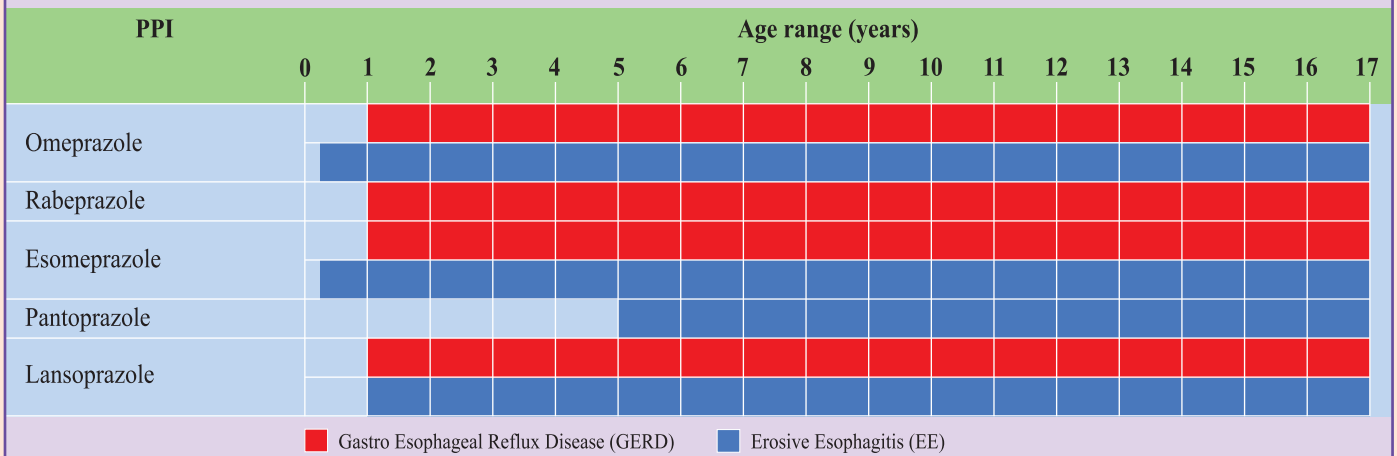
Rabeprazole: The safety and effectiveness of rabeprazole have been established in pediatrics patient 1 to 17 years of age for the treatment of GERD. For 1 to 11 years of age rabeprazole sprinkle form is used and 12 to 17 years rabeprazole tablet is used.

Esomeprazole: The safety and effectiveness of esomeprazole have been established in pediatric patients 1 to 17 years of age for the treatment of symptomatic GERD and healing of EE. The effectiveness of esomeprazole has been also demonstrated in patients 1 month to less than 1 year of age for short term treatment of EE due to acid mediated GERD.

Pantoprazole: The safety and effectiveness of pantoprazole for short term treatment of EE associated with GERD have been established in pediatric patients 5 to 17 years of age.

Lansoprazole: The safety and effectiveness of lansoprazole have been established in pediatric patients 1 to 17 years of age for short term treatment of symptomatic GERD and EE.

Figure 1: FDA approved pediatric age ranges and indications for proton pump inhibitors



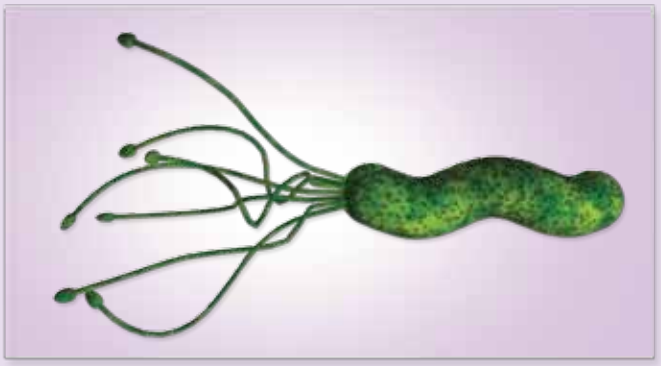
Note: Different dosage form (e.g., oral suspension, capsule, sprinkle and tablet) of PPIs were used in this pediatric population

References: 1. *Originator data sheet of PPIs: Prilosec, Nexium, Protonix, Prevacid & Aciphex*
2. *https://goo.gl/TMxMpH*

AMERICAN COLLEGE OF GASTROENTEROLOGY

ACG clinical guideline: Treatment of *Helicobacter pylori* infection

Helicobacter pylori (H. pylori) infection is a common worldwide infection that is an important cause of peptic ulcer disease and gastric cancer. *H. pylori* may also have a role in uninvestigated and functional dyspepsia, ulcer risk in patients taking low dose aspirin or starting therapy with a non steroidal anti-inflammatory medication, unexplained iron deficiency anemia, and idiopathic thrombocytopenic purpura. While choosing a treatment regimen for *H. pylori,* patients should be asked about previous antibiotic exposure and this information should be incorporated into the decision making process. For first line treatment, clarithromycin triple therapy should be confined to patients with no previous history of macrolide exposure who reside in areas where clarithromycin resistance amongst *H. pylori* isolates is known to below. Most patients will be better served by first line treatment



with bismuth quadruple therapy or concomitant therapy consisting of a PPI, clarithromycin, amoxicillin, and metronidazole. According to American College of Gastroenterology (ACG), details of first line regiment for *H. pylori* infection are given in Table 1 regarding first line regimen for *H. pylori* infection.

Table 1: First line regimen for *H. pylori* infection

Regimen	Drugs (doses)	Dosing frequency	Duration (days)
Clarithromycin triple	PPI (standard or double dose)	BID	14
	Clarithromycin (500mg)		
	Amoxicillin (1gm) or Metronidazole (500mg TID)		
Bismuth quadruple	PPI (standard dose)	BID	10-14
	Bismuth subcitrate (120-300mg) or subsalicylate (300mg)	QID	
	Tetracycline (500mg)	QID	
	Metronidazole (250-500mg)	QID (250) TID to QID (500)	
Concomitant	PPI (standard dose)	BID	10-14
	Clarithromycin (500mg)		
	Amoxicillin (1gm)		
	Nitroimidazole (500mg)		
Sequential	PPI (standard dose) + Amoxicillin (1gm)	BID	5-7
	PPI, Clarithromycin (500mg) + Nitroimidazole (500mg)		
Hybrid	PPI (standard dose) + Amoxicillin (1gm)	BID	7
	PPI, Amoxicillin, Clarithromycin (500mg), Nitroimidazole (500mg)		
Levofloxacin triple	PPI (standard dose)	BID	10-14
	Levofloxacin (500mg)	QD	
	Amoxicillin (1gm)	BID	
Levofloxacin sequential	PPI (standard or double dose) + Amoxicillin (1gm)	BID	5-7
	PPI, Amoxicillin, Levofloxacin (500mg QD), Nitroimidazole (500mg)		
LOAD	Levofloxacin (250mg)	QD	7-10
	PPI (double dose)	QD	
	Nitazoxanide (500mg)	BID	
	Doxycycline (100mg)	QD	

Reference: *The American Journal of Gastroenterology, Feb 2017, Vol. 112*

FDA grants pediatric indication for 2 HCV drugs

The FDA approved new indications for sofosbuvir and ledipasvir-sofosbuvir to treat Hepatitis C virus (HCV) in children from 12 to 17 years of age. These are the first direct acting antiviral treatments approved for children and adolescents with HCV. DAA (Direct acting antiviral) drugs reduce the amount of HCV in the body by preventing the virus from multiplying and in most cases, they cure HCV. These approvals provide pediatric treatment options for six major genotypes of HCV. Ledipasvir-sofosbuvir is indicated for the treatment of pediatric patients 12 years of age and older or weighing at least 77 pounds with HCV genotype 1, 4, 5 or 6 infection without cirrhosis or with mild cirrhosis. Sofosbuvir in combination with ribavirin is indicated for the treatment of pediatric patients 12 years of age and older or weighing at least 77 pounds with HCV genotype 2 or 3 infection without cirrhosis or with mild cirrhosis. FDA recommended to screen all patients for evidence of current or prior HBV infection before starting treatment with ledipasvir-sofosbuvir or sofosbuvir.

"The approvals of sofosbuvir and ledipasvir-sofosbuvir for pediatric patients will enable adolescents to finally benefit from interferon free treatment for HCV infection and these therapies address a significant unmet medical need and represent an important advance for HCV infected adolescents" said Karen Murray, MD, a professor of pediatrics at the University of Washington School of Medicine and Seattle Children's Hospital.

Reference: *Gastroenterology & Endoscopy News, Aprl 10, 2017*