

EDITORIAL

New FDA approved therapy for *Helicobacter pylori* infection

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Abstract

Approximately 90% of the gastric cancer cases have been linked to *Helicobacter pylori* (*H. pylori*). *H. pylori* remains a real threat, infecting approximately 4 billion people in 2015 around the globe. It is also known to colonize the gastrointestinal mucosa of almost half the human population. Currently, the most common treatment for *H. pylori* infection is the first line clarithromycin-based triple therapy or a quadruple therapy replacing clarithromycin with new antibiotics. Vonoprazan-based triple therapy has been reported to have greater efficacy than a proton pump inhibitor-based triple therapy for *H. pylori*. In 2022, the U.S. Food and Drugs Administration approved the vonoprazan-based triple and dual therapies. This latest treatment represents a proof of concept for the development of even more efficient and advanced treatments targeting *H. pylori*, in order to significantly decrease gastrointestinal-related pathologies.

Keywords

Vonoprazan, clarithromycin, amoxicillin, *H. pylori*; vonoprazan-based triple therapy.

Approximately 90% of the gastric cancer cases have been linked to *Helicobacter pylori* (*H. pylori*). *H. pylori* remains a real threat that infected approximately 4 billion people in 2015 around the

globe. It is also known to colonize the gastrointestinal mucosa of almost half the human population^{1,2}.

Typical treatment for a diagnosed *H. pylori* infection is a first line clarithromycin-based triple treatment or a quadruple treatment replacing clarithromycin with new antibiotics, which lead to eradication of the infection in a majority of the patients, but not all. Thus, new more efficient therapeutics strategies for *H. pylori* eradications are required. The vonoprazan-based triple treatment, was reported to be more efficient for the treatment of *H. pylori* than the proton pump inhibitor-based triple treatment and because of that, the US FDA approved it in 2022 for a better chance to eradicate *H. pylori*³. The vonoprazan-based triple therapy includes clarithromycin, amoxicillin and potassium-competitive acid blocker (vonoprazan)⁴.

Most of the *H. pylori* risk factors are related to the geographical regions, ethnicity, socioeconomic status and the emigration from countries with high prevalence of *H. pylori*. Recently, the infection with *H. pylori* has been decreasing in highly industrialized countries, while remaining at a high level in developing countries^{1,2,5}.

H. pylori is gram-negative bacillus that is microaerophilic and has a flagella¹. *H. pylori* is considered to be responsible or associated with chronic gastritis, peptic ulcer, gastric mucosa associated lymphoid tissue (MALT) lymphoma and distal gastric adenocarcinoma. *H. pylori* promotes

gastric cells proliferation that can develop into carcinogenesis.

Clarithromycin is an important macrolide antibiotic for treating *H. pylori* disease. As for most of the antibiotics, resistance can occur and the treatment can fail⁶. Amoxicillin is an antibiotic that enters in the penicillin drug class that is in beta-lactam family of antibiotics⁷. Amoxicillin is also a penicillin class essential antibiotic used for treating *H. pylori*, being used in treatments such as triple therapy (amoxicillin, clarithromycin and proton pump inhibitor) and vonoprazan-based triple treatment (amoxicillin, clarithromycin and vonoprazan)⁸. Vonoprazan fumarate is a potassium competitive acid blocker, which inhibit the H⁺, K⁺ adenosine triphosphatase (ATPase), having as the outcome the suppression of the gastric acid secretion³.

Vonoprazan-triple based treatment is more efficient than the standard treatment based on a proton pump inhibitor-triple treatment for *H. pylori* patients⁹. A clinical study enrolling *H. pylori* infected patients who did not have a clarithromycin or amoxicillin resistant strain, shows that the eradication percentages were 84.7% with amoxicillin, clarithromycin and vonoprazan (Voquezna Triple Pak), 78.5% for amoxicillin and vonoprazan fumarate (Voquenza Dual Pak), while for the lansoprazole-based triple therapy the eradication rate was 78.8%¹⁰.

In 2022, the U.S. Food and Drugs Administration (FDA) approved amoxicillin, clarithromycin and vonoprazan (Voquezna Triple Pak) and amoxicillin and vonoprazan (Voquenza Dual Pak) for the treatment of *H. pylori* patients in the adult population¹¹. After a randomized, controlled, double clinical trial study was performed (ClinicalTrials.gov Identifier: NCT04167670). Amoxicillin, clarithromycin and vonoprazan triple pack and amoxicillin and vonoprazan fumarate dual pack should only be used to treat or to prevent infections that are caused by susceptible bacteria, because infected people need to effectively respond to the treatment and to reduce the chance of developing drug-resistant bacteria. If susceptibility information is known, the treatment should be accordingly adapted¹¹.

Recommended adult oral dosage of amoxicillin, clarithromycin and vonoprazan triple pack is amoxicillin 1000 mg plus vonoprazan 20 mg plus clarithromycin 500 mg, twice a day and 12 hours

apart. The recommended adult oral dosage of amoxicillin and vonoprazan fumarate dual pack is vonoprazan 20 mg twice a day and amoxicillin 1000 mg, three times daily, for 14 days. The consumption of food when the treatment is taken is not necessary¹¹.

Vonoprazan-based triple therapy is a promising new anti-*H. pylori* therapy and represents a proof of concept for the development of even more efficient and advanced treatments targeting *H. pylori*, in order to significantly decrease gastrointestinal-related pathologies, such as gastric cancer, chronic gastritis and peptic ulcer.

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Conflict of Interest

The author declares that there are no conflicts of interest.

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