**Niewęgłowski Kacper, Wilczek Natalia, Rycharski Michał, Niewęgłowska Julita. Vonoprazan - a new drug for inhibiting gastric acid secretion. Journal of Education, Health and Sport. 2022;12(8):661-670. eISSN 2391-8306. DOI http://dx.doi.org/10.12775/JEHS.2022.12.08.068**
**https://apcz.umk.pl/JEHS/article/view/JEHS.2022.12.08.068**
**https://zenodo.org/record/7012324**

**The journal has had 40 points in Ministry of Education and Science of Poland parametric evaluation. Annex to the announcement of the Minister of Education and Science of December 21, 2021. No. 32343. Has a Journal's Unique Identifier: 201159. Scientific disciplines assigned: Physical Culture Sciences (Field of Medical sciences and health sciences); Health Sciences (Field of Medical Sciences and Health Sciences).**

**Punkty Ministerialne z 2019 - aktualny rok 40 punktów. Załącznik do komunikatu Ministra Edukacji i Nauki z dnia 21 grudnia 2021 r. Lp. 32343. Posiada Unikatowy Identyfikator Czasopisma: 201159. Przypisane dyscypliny naukowe: Nauki o kulturze fizycznej (Dziedzina nauk medycznych i nauk o zdrowiu); Nauki o zdrowiu (Dziedzina nauk medycznych i nauk o zdrowiu).**



**Received: 05.08.2022. Revised: 07.08.2022. Accepted: 20.08.2022.**

# Vonoprazan - a new drug for inhibiting gastric acid secretion

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## Abstract

Introduction and purpose

Vonoprazan is a potassium-competent acid blocker (P-CAB). It has the potential to be an alternative to proton pump inhibitors (PPIs) as it inhibits hydrochloric acid secretion. The mechanism of action is different than PPIs - vonoprazan reversibly inhibits gastric $H^+$, $K^+$-ATPase, while PPIs irreversibly. Vonoprazan is approved for use in Japan and the US. The aim of the study was to review articles on the use of vonoprazan instead of PPIs in the treatment of acid-related gastrological diseases and to present the results obtained.

## A brief description of the state of knowledge

Vonoprazan is used in the treatment of acid-related gastrological diseases. The 20 mg dose is suitable for most diseases, such as treatment of ulcers during low-dose aspirin treatment, post-endoscopic submucosal dissection (post-ESD) ulcers, erosive esophagitis (EE) in gastroesophageal reflux disease (GERD), and *Helicobacter pylori* eradication.

**Summary**
Researches suggest that the drug is an alternative for PPIs and can be used instead of them. The main advantage of this drug over PPIs is that it works faster, more potent and long-lasting. Studies suggest that vonoprazan can be use to treatment of the acid-related diseases and may be a better choice than PPIs. Vonoprazan may have a particular use in the treatment of PPI-refractory GERD. In post-ESD ulcers, a significant benefit in treatment effects of vonoprazan over PPIs cannot be clearly concluded.

**Keywords:** Vonoprazan; Potassium-competitive acid blocker; Proton Pump Inhibitors; Acid-related diseases

## 1. Introduction and purpose

Drugs inhibiting the secretion of hydrochloric acid are mainly used in the treatment of gastrological diseases - the acid-related diseases, such as GERD (gastroesophageal reflux disease), peptic ulcer disease and for the eradication of *Helicobacter pylor*i. The standard treatment for these conditions are drugs called proton pump inhibitors (PPIs) [1,2].
Vonoprazan is a drug belongs to the potassium-competitive acid blockers (P-CAB) group and is a potential alternative to PPIs. The effect of the drug is similar to the PPIs effect. Vonoprazan is an inhibitor of hydrochloric acid secretion, but this is done in a different way than PPIs - by quick, long-lasting and reversible inhibition of gastric $H^+$, $K^+$-ATPase, while PPIs bind irreversibly. It is stable in an acidic pH and does not require an acidic environment for activation. The drug is used orally [3-5].
In December 2014, vonoprazan was approved in Japan by the Japanese Ministry of Health, Labor and Welfare. The approval was for the treatment of acid-related diseases, e.g., gastric ulcers or *H. pylori* eradication [6]. In the U.S., two preparations containing vonoprazan were available on the market in May 2022. The products are compounded preparations containing amoxicillin or amoxicillin and clarithromycin, used in the eradication of *H. pylori* [7].
A trial in healthy men shows that doses of vonoprazan 10-40 mg are effective – rapidly and potently inhibiting hydrochloric acid secretion. The drug is well tolerated and has no significant side effects [8]. Food does not affect the absorption and action of the drug [9].
T. Kasai et al. studied the impact of Body Mass Index (BMI) on the success of second-line therapy for *H. pylori* eradication. They found that patients with higher BMI were more successful in *H. pylori* eradication than patients with lower BMI [10].
The aim of the study was to review articles on the use of vonoprazan instead of PPIs in the treatment of the acid-related gastrological diseases and to present the results obtained.

## 2. Description of the state of knowledge

### 2.1. Vonoprazan vs. PPIs

Vonoprazan 20 mg shows potent and longer-lasting inhibition of acid secretion than rabeprazole 40 mg [11], vonoprazan also had a faster and potent effect than esomeprazole 20 mg and rabeprazole 10 mg [12]. In comparison to lansoprazole, vonoprazan also inhibits acid secretion more quickly and potently [13], furthermore, K. Ohkuma et al. concluded similarly using doses of vonoprazan 20 mg and lansoprazole 30 mg [14].

### 2.2. Vonoprazan and gastrin level

Vonoprazan affects the increase of gastrin levels in the blood. Lafutidine 10 mg can reduce this effect. In that case, vonoprazan 10 mg will be enough to inhibit acid secretion and the gastrin level in the blood will not be too excessive [15]. The use of pirenzepine 75 mg with vonoprazan 10 mg can effectively inhibit gastric acid secretion, and prevent hypergastrinemia [16].

### 2.3. Vonoprazan and aspirin

In a phase 3 clinical trial, T. Kawai et al. found that vonoprazan 10 and 20 mg had similar effects to lansoprazole 15 mg in preventing peptic ulcer recurrence during patients treated with low-dose aspirin. Furthermore, a treatment with vonoprazan 10 mg reported a lower rate of peptic ulcer recurrence than with vonoprazan 20 mg [17]. Phase 2 of another study found no drug interaction between vonoprazan and low-dose aspirin, and the drug was well tolerated [18]. Even with the use of high doses of aspirin, vonoprazan is also effective and safe in preventing ulcer recurrence associated with NSAID treatment, this was the finding concluded by Y. Mizokami et al. They compared the effect of vonoprazan 10 mg to lansoprazole 15 mg, both drugs had similar efficacy and safety. Aspirin 1000 mg was used as the NSAID in the study [19].
H. Tsujimoto et al. in a randomized controlled trial (RCT) investigated that in patients treated with low-dose aspirin, the use of vonoprazan 10 mg led to an increase in Lactobacillales in gut microbiota. The effect was also seen with esomeprazole 20 mg, but to a lower extent. The increase in gastrin levels was also higher in the vonoprazan group than in the esomeprazole group [20].

### 2.4. Vonoprazan and endoscopic submucosal dissection (ESD)

Clinical trial conducted by T. Kagawa et al. proved that vonoprazan is effective in reducing post-ESD bleeding and is more effective than PPIs [21]. Y. Hidaka et al. investigated RCT that proved that for patients treated with antithrombotic drugs, vonoprazan is more effective in preventing bleeding from post-ESD gastric ulcers than PPIs [22].
A phase II study by K. Hamada et al. suggests that vonoprazan 20 mg is effective in delayed bleeding after ESD in patients with a post-ESD gastric ulcer.

The researchers conclude that a phase III study is needed to definitively determine the efficacy of vonoprazan versus PPIs [23].
In a trial by T. Ishida et al. found that vonoprazan had efficacy similar to PPIs in preventing a delayed bleeding after ESD. The healing time of an post-ESD ulcer was significantly quicker with vonoprazan [24]. I. Tsuchiya et al. also reported that vonoprazan 20 mg was significantly more effective than esomeprazole 20 mg for the healing of post-ESD gastric ulcers [25].
T. Ichida conducted a RCT comparing vonoprazan 20 mg plus rebamipide 300 mg and esomeprazole 20 mg plus rebamipide 300 mg and they found that the combination with vonoprazan was no more effective in healing post-ESD ulcers than the combination with esomeprazole [26]. A. Hirai et al. compared the effects of vonoprazan 20 mg and lansoprazole 30 mg in treating post-ESD ulcers and found that both drugs had similar efficacy [27]. D. Kawai et al. similarly reported that vonoprazan may not be a better choice than lansoprazole in ulcer healing after ESD; furthermore, the 4-week ulcer healing rate was not significantly higher in either group [28].
H. Komori et al. proved that vonoprazan is not more effective than rabeprazole - when using rabeprazole at a dose of 10 mg, ulcer healing after endoscopic submucosal dissection was faster than with vonoprazan 20 mg [29].

### 2.5. Vonoprazan and *H. pylori* eradication

Vonoprazan 20 mg is effective, well tolerated and safe in triple therapy [30, 31] and in quadruple therapy with bismuth [32]. The safety was also proven in children [33].
The use of vonoprazan 20 mg in triple therapy instead of PPIs (omeprazole 20 mg or esomeprazole 20 mg or rabeprazole 20 mg) reduced the duration of therapy from 14 days to 7 days [34-36].
The significant superiority of vonoprazan over PPIs was confirmed by H. Ozaki et al. The eradication rate was assessed by an urea breath test. The researchers concluded that vonoprazan is expected to be the drug of first line in the future [37]. M. Maruyama et al. reported similar results and the same conclusion [38].
W. D. Chey et al. conducted an RCT on patients from Europe and the US. Researchers compared 3 treatment regimens: 1) triple therapy with vonoprazan 20 mg, 2) triple therapy with lansoprazole 30 mg and 3) dual therapy with vonoprazan 20 mg. Vonoprazan was superior to lansoprazole as evidenced by higher eradication rates in these groups [39].
B. F. Zuberi et al. compared standard triple therapy with PPI (omeprazole 20 mg) vs. dual therapy with vonoprazan 20 mg. Stool *H. pylori* antigen was checked after treatment in both groups of patients and the rate of negative results was similar [40]. T. Furuta et al. proved that dual therapy with vonoprazan 20 mg results a similar eradication rate to triple therapy with vonoprazan 20 mg. The duration of therapy is 7 days [36].
In Japan, where vonoprazan is available in the market, an increase in the success rate of triple therapy was observed after it was introduced [41].

### 2.6. Vonoprazan and duodenal ulcers (DU)

In trials conducted by X. Hou et al. [42] and H. Miwa et al. [43] found vonoprazan 20 mg to be no inferior to lansoprazole 30 mg in the treatment of DU, with similar side effects. They also observed that gastrin levels were higher in patients treated with vonoprazan.

### 2.7. Vonoprazan and GERD

Vonoprazan 20 mg is effective and no inferior than PPIs in the treatment of erosive esophagitis (EE) and significantly superior in the treatment of severe EE [44-46]. The drug also have efficacy as on-demand therapy as maintenance therapy for mild reflux esophagitis [47]. For the treatment of patients with mild EE, the initial dose of vonoprazan might be 10 mg [48]. In a trial by S. Matsuda et al. [49], the drug was successfully used as a maintenance treatment for erosive GERD. In this case, doses of 10 mg every second day were effective.
Vonoprazan may have a particular use in the treatment of PPI-refractory GERD, in which it is effective at a dose of 20 mg [50-52].
For the treatment of healed reflux esophagitis (RE), vonoprazan 10 mg or 20 mg is as effective as lansoprazole 15 mg [53, 54].
A trial by Y. Kinoshita et al. comparing vonoprazan 10 mg vs. placebo showed that vonoprazan was not superior to placebo in terms of heartburn-free days, but was significantly superior in terms of heartburn resolution after taking it [55]. Vonoprazan 20 mg causes faster heartburn relief than lansoprazole 30 mg [56]. S. Shinozaki et al. proved that vonoprazan 10 mg is effective in reducing GERD symptoms such as epigastric pain, postprandial distress, constipation and diarrhea [57].

## 3. Summary

Vonoprazan is a drug approved for use in Japan and the US. Researches suggest that the drug is an alternative for PPIs and can be used instead of them. The main advantage of this drug over PPIs is that it works faster, more potent and long-lasting. Studies suggest that vonoprazan can be use to treatment of the acid-related diseases and may be a better choice than PPIs. Vonoprazan may have a particular use in the treatment of PPI-refractory GERD. In post-ESD ulcers, a significant benefit in treatment effects of vonoprazan over PPIs cannot be clearly concluded.

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