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**Original article**

# A retrospective study on drug regimens for Helicobacter Pylori treatment King Chulalongkorn Memorial Hospital, Thai Red Cross Society

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## Abstract

***Background:*** Currently, each country has clinical guidelines for treating Helicobacter pylori (H. pylori) infection. Therefore, analysis and follow-up of treatment results of each drug regimen are extremely important, since they could lead to selection of effective drug regimens that have high eradication rate and excellent safety profile. However, since most regimens contain at least two antibiotics, Helicobacter pylori treatment may cause development of antibiotic resistance and imbalance of bacteria in the gut. The latter situation can also lead to further gastrointestinal disease.

***Objective:*** This study aimed to investigate drug regimens for treatment of H. pylori.

***Methods:*** Retrospective data on patients who were diagnosed by ICD-10 criteria for H. pylori infection and received a prescription for treatment, between 1st January 2022 and 31st December 2022, by the researchers. The data from the electronic database, which was created specifically for research purpose, were screened and confidential.

***Results:*** There were 340 patients diagnosed with H. pylori infection. One hundred thirty - three (39.1%) were male, while 207 (60.9%) were female. The first regimens that doctors prescribed were standard triple therapy, bismuth quadruple therapy, levofloxacin-based triple therapy, sequential triple therapy, and vonoprazan-based therapy. Standard triple therapy was the most commonly prescribed first regimen. Regimens that doctors prescribed after failure of the first regimen were levofloxacin-based triple therapy and bismuth quadruple therapy. This study found that the eradication rates for the first and second regimens were 81.2% and 81.8%, respectively. The eradication rate of H. pylori was calculated from patients who came to their follow-up visits. There were 63 and 11 patients who did not come to the first and second post-treatment follow-up visits, respectively.

***Conclusion:*** Standard triple therapy remained the mainstay of treatment H. pylori. The main problem found in this study was patients' unawareness of the importance of follow-up visits to confirm eradication of H. pylori. Therefore, pharmacists play an important role in giving advice on taking medicine continuously and emphasizing the importance of post-treatment follow-up visits.

***Keywords:*** Drug regimen, helicobacter pylori, retrospective study.

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Helicobacter pylori (H. pylori) is a gram-negative bacterium that colonizes the lining of human stomach. In Thailand, the data on prevalence of H. pylori infection had been collected from 2004 to 2012. The overall incidence of the infection was 34.1% and can vary from region to region.[1] Most infected patients develop chronic gastritis but show no symptoms. H. pylori infection increases the risks of gastritis, peptic ulcer, and gastric cancer. Eradication of H. pylori can reduce the incidence of gastric cancer.[2]

Currently, each country has clinical guidelines for treating H. pylori infection, with a number of drug regimens available to combat the growing problem of antibiotic resistance in H. pylori. Drug regimen used can vary depending on public health policy and access to treatment. The introduction of potassium-competitive acid blockers (P-CABs), such as vonoprazan, can reduce the period of treatment from 14 days to only 7 - 10 days. [2] In 2018, vonoprazan from Japan was introduced to Thailand. As a result, vonoprazan is being increasingly prescribed as a replacement for proton pump inhibitors in the mainstream regimen, as well as an alternative regimen, vonoprazan-amoxycillin dual therapy.

Therefore, this study aimed to investigate the patterns of drug regimens for finding the regimen that effectively eradicates the infection and provides patients with the highest level of safety.

## Materials and methods

### *Study design*

A retrospective descriptive study conducted by reviewing patient medical history and follow-up information recorded in the electronic medical record. The study protocol has been approved by the Ethics Committee, Faculty of Medicine, Chulalongkorn University (IRB no. 0435/66).

### *Population and sample selection*

Patients infected with H. pylori were enrolled and received a drug regimen to treat H. pylori infection. Inclusion criteria were as follows: all patients who received a drug regimen for the treatment of H. pylori infection at King Chulalongkorn Memorial Hospital, Thai Red Cross Society, between 1st January 2022 and 31st December 2022, whose disease codes by 10th revision of the International statistical classification of diseases and related health problems (ICD-10) were B980 Helicobacter pylori [H. pylori] as the cause of diseases classified to other chapters. Doctors identified patients as H. pylori infection by biopsy or urea breath test. Exclusion criteria were as follows: patients whose ICD-10 disease codes did not meet the specified criteria and patients with incomplete information in the electronic medical record system.

### *Data collection tools*

Electronic medical records from King Chulalongkorn Memorial Hospital, Thai Red Cross Society, with the disease code by ICD-10 of B980 Helicobacter pylori [H. pylori] as the cause of diseases classified to other chapters (The medical records had been modified and patient information had been concealed in the part where the patient's identity could be identified, in order to protect the rights and personal information of the patient which was in accordance with the personal data protection act of 2019)

### *Statistical analysis*

Satisfied analysis was conducted using statistical package for the social sciences (SPSS) software version 22.0 for Windows. General basic information was analyzed using descriptive statistics: numbers, percentages, means, and standard deviations. The statistical analysis was employed to compare the proportions of categorical data: drug regimens used to treat H. pylori infection and duration of treatment, with the statistical significance level set at $P < 0.05$.

## Results

### *General information*

There were 340 patients diagnosed with H. pylori infection. One hundred and thirty-three (39.1%) were male, while 207 (60.9%) were female, with an average age of 59.5 ± 12.7 years. Sixteen (4.7%) of those patients had a previous treatment for H. pylori infection.

From 340 patients, diagnosis of H. pylori infection was done by endoscopy-based diagnosis/ campylobacter-like organism test (CLO test), followed by biopsy in 319 patients (93.8%), and urea breath test (UBT) in 21 patients (6.2%).

This study found that there were five drug regimens used for treating H. pylori infection: standard triple therapy, bismuth quadruple therapy, levofloxacin-based triple therapy, sequential triple therapy, and vonoprazan-based therapy. The most common prescribed regimen was standard triple therapy, followed by bismuth quadruple therapy, as the details shown in **Table 1.**

**Table 1.** Drug regimens used to treat H. pylori infection and result.

| H. pylori treatment regimen | N (%) | Treatment success n (%) | Treatment failure n (%) |
|---|---|---|---|
| Standard triple therapy | 234 (68.8) | 156 (66.7) | 33 (14.1) |
| Bismuth quadruple therapy | 33 (9.7) | 21 (63.6) | 7 (21.2) |
| Levofloxacin-based therapy | 27 (8.0) | 18 (66.7) | 5 (18.5) |
| Sequential triple therapy | 14 (4.1) | 7 (50.0) | 2 (14.3) |
| Vonoprazan-based therapy | 32 (9.4) | 23 (71.9) | 5 (15.6) |
| **Total** | **340 (100.0)** | | |

**Table 2.** Drug regimens for treatment of H. pylori infection after failure of the first treatment.

| Drug regimen | N (%) |
|---|---|
| Levofloxacin-based therapy | 18 (40.9) |
| Bismuth quadruple therapy | 13 (29.5) |
| Vonoprazan-based therapy | 6 (13.6) |
| Standard triple therapy | 4 (9.1) |
| Sequential therapy | 2 (4.6) |
| Concomitant therapy | 1 (2.3) |
| **Total** | **44 (100.0)** |

The eradication rate of H. pylori was calculated from 277 patients who came to their follow-up visits. Two hundred and thirty-five (81.2%) of them had successfully eradicated H. pylori, while 52 patients (18.8%) failed to eradicate H. pylori. Sixty-three patients did not show up for their follow-up appointments.

The study also showed that all the five regimens provided treatment results that were not significantly different ($P = 0.446$). Out of a total of 340 patients, 277 took the medication for the entire treatment period. The remaining 63 patients could not be followed up due to various reasons, such as loss to follow-up, patients were continuing treatment elsewhere.

For vonoprazan-based regimens, a proton-pump inhibitor is replaced by vonoprazan. There were three of these regimens prescribed, with 10 patients received standard triple therapy, while 14 patients received bismuth quadruple therapy, and eight patients received levofloxacin-based therapy. On success rates of these three regimens, eight patients from standard triple therapy group had successfully eradicated H. pylori infection (two patients were not tested for UBT), while nine patients from bismuth quadruple therapy group had successfully eradicated the infection (two patients were not tested for UBT, and the treatment failed in three patients), and six patients from levofloxacin-based therapy group had successfully eradicated the infection (the treatment failed in 2 patients).

This study found that there were two treatment durations for H. pylori infection: 10 days and 14 days. In the group that received the 14-days treatment, 221 patients had successfully eradicated the infection, while 51 patients failed to eradicate the infection. In the group that received the 10 days treatment, four patients had successfully eradicated the infection, while one patient failed to eradicate the infection. The two treatment durations were not significantly different ($P = 0.990$).

Out of 52 patients who had failed to eradicate H. pylori infection after the first treatment, 44 received further treatment. There were six drug regimens that doctors prescribed to patients who had failed to eradicate the infection the first time. Levofloxacin-based triple therapy was the most often prescribed regimen, followed by bismuth quadruple therapy, as detailed in **Table 2.**

The eradication rate of the second treatment was calculated from 33 patients who came for their follow-up visits. Twenty-seven (81.8%) of them had successfully eradicated H. pylori, while six patients (18.2%) failed to eradicate H. pylori. Eleven patients from the levofloxacin-based therapy group had successfully eradicated the infection, along with 12 patients from the bismuth quadruple therapy group, two patients from the standard triple therapy group, one patient from the sequential therapy group, and one patient from the concomitant group. Eleven patients did not show up for their follow-up appointments.

To monitor treatment results, from 340 patients, 15 of them did not come to their follow-up appointments. Fourteen of those subjects did not show up, while one patient continued treatment at another hospital. The average duration between their first visit and follow-up visit was 90.0 ± 43.0 days or 13.0 ± 6.0 weeks.

## Discussion

In this study found that gastrointestinal endoscopy with biopsy for H. pylori was the most common way to confirm the infection before prescribing a treatment regimen for H. pylori. There were five drug regimens prescribed: standard triple therapy, bismuth quadruple therapy, levofloxacin-based therapy, sequential therapy, and vonoprazan-based therapy. One patient, who had failed the initial treatment with levofloxacin-based regimen, received concomitant therapy. There were two treatment durations for H. pylori infection: 10 days and 14 days.

Once a patient was diagnosed with H. pylori infection, standard triple therapy was often the doctor's first choice of treatment, followed by bismuth quadruple therapy. The prescription of standard triple therapy was consistent with the 2015 Thai clinical practice guidelines for the diagnosis and treatment of patients with H. pylori infection[3] and report from the Maastricht V consensus conference in 2014.[4] Bismuth quadruple therapy is recommended as first-line treatment in 2018 by Chinese clinical practice guidelines for the diagnosis and treatment of patients with Helicobacter pylori infection.[5] A total of 234 patients received standard triple therapy, but only 189 patients showed up for their follow-up appointments; 156 patients had successfully eradicated H. pylori, while 33 patients failed to eradicate the infection, representing an eradication rate of 82.5%, which was similar to the data from Thailand in 2015 that reported an eradication rate of 85.0%. [6] One of the reasons for treatment failure, aside from poor adherence, is some strains of H. pylori are resistant to antibiotics. A study in European countries of Megraud F, *et al* [7] found that the use of macrolides and quinolones in the community was associated with development of drug resistance, which made it necessary to test the susceptibility of H. pylori to antibiotics before starting the treatment.

In Japan [8], Vonoprazan, a new acid-suppressing drug with a fast and long-lasting effect, belongs to a new class of drugs called potassium-competitive acids blocker (P-CAB); has been used since 2015. It is also used, in the place of a proton pump inhibitor (PPI), as one of the main drugs in triple therapy, along with two antibiotics, amoxycillin and clarithromycin. This regimen is used as first-line treatment with shorter treatment duration of only 7 to 10 days. A randomized controlled study found that vonoprazan-based triple therapy had a higher H. pylori eradication rate of 89.0% - 93.0%. [9] The eradication rate was more than 80.0% in clarithromycin-resistant strains. [10] In this study, there were 32 patients who received regimens containing vonoprazan instead of a PPI. Ten of those received standard triple therapy, 14 received bismuth quadruple therapy, and eight received levofloxacin-based therapy. Two patients were treated for 10 days, while the remaining 30 were treated for 14 days, which was not in line with the Japanese medical practice guidelines and the study of Okubo H, *et al* [11], which suggest a treatment period of only seven days. Out of a total of 32 patients, eradication rate of H. pylori was calculated from only 20 patients who showed up for their follow-up appointments; 16 (80.0%) of those patients had successfully eradicated H. pylori, while four patients (20.0%) failed to eradicate the infection; 12 patients did not show up for their follow-up appointments. This study reported an eradication rate of H. pylori that was lower than that from the Japanese study, so further studies might be needed. Clinical practice guidelines and drug regimens currently used to treat H. pylori infection are shown in **Tables 3 and 4.**

All five drug regimens: standard triple therapy, bismuth quadruple therapy, levofloxacin-based therapy, sequential therapy, and vonoprazan-based triple therapy, provided treatment results that were not significantly different. The two treatment durations: 10 day and 14 day, were also not significantly different. Therefore, selection of drug regimen can still be based on the 2015 Thai clinical practice guidelines for diagnosis and treatment of patients with Helicobacter pylori infection. But in terms of duration of treatment, it may be necessary to consider other factors to decide whether the drug should be given for a period of 10 days or 14 days.

Out of 234 patients, there were nine patients with a history of allergic reaction to penicillin who were prescribed standard triple therapy with metronidazole replacing amoxicillin, which was in line with the 2015 Thai clinical practice guidelines for diagnosis and treatment of patients with Helicobacter infection

**Table 3**. Drug regimens currently used for treatment of H. pylori infection.

| Clinical practice guidelines | Drug regimen | Duration of treatment (days) |
|---|---|---|
| ACG clinical guideline[12] | In areas with low CLA resistance (< 15.0%) or in patients who have never received a macrolide before | |
| | Standard triple therapy (PPI + CLA + AMO/MET) | 14 |
| | In areas with high CLA resistance (> 15.0%) or in patients who have received a macrolide before | |
| | Bismuth quadruple therapy (PPI + bismuth + TET + MET) | 10 - 14 |
| | Concomitant quadruple therapy (PPI + CLA + AMO + MET) | 10 - 14 |
| Maastricht V/ Florence consensus report[4] | In areas with low CLA resistance (< 15.0%) (PPI + CLA + AMO/MET) | 14 |
| | In areas with high CLA resistance (> 15.0%) | |
| | Bismuth quadruple therapy (PPI + bismuth + 2ATB) | 14 |
| | Concomitant quadruple therapy (PPI + CLA + AMO + MET/TIN) | 14 |
| Toronto consensus[13] | In areas with low CLA resistance (< 15.0% | 14 |
| | Standard triple therapy (PPI + CLA + AMO/MET) | |
| | In areas with high CLA resistance (> 15.0%) | |
| | Bismuth quadruple therapy (PPI + bismuth + TET + MET) | 14 |
| | Concomitant quadruple therapy (PPI + CLA + AMO + MET) | 14 |
| Fifth Chinese national consensus report [5] | Bismuth quadruple therapy (PPI + bismuth + 2ATB) | 10 - 14 |
| Korean guideline 2020 [14] | Standard triple therapy (PPI + CLA + AMO) | 14 |
| | Sequential therapy (PPI + AMO for 5 days, followed by PPI + CLA + MET for 5 days) | 10 |
| | Concomitant quadruple therapy (PPI + CLA + AMO + MET) | 10 |
| Japanese guideline 2016[8] | Standard therapy (PPI + AMO + CLA/MET) or | 7 |
| | Vonoprazan triple therapy (P-CAB + AMO + CLA/MET) | 7 |
| Thailand consensus 2015[3] | First-line treatment | |
| | Standard triple therapy (PPI + CLA + AMO/MET) | 10 - 14 |
| | Sequential therapy (PPI + AMO for 5 days, followed by PPI + CLA + MET for 5 days) | 10 |
| | Concomitant quadruple therapy (PPI + CLA + AMO + MET) | 10 |
| | Second-line treatment | 14 |
| | Quadruple therapy (PPI + bismuth + 2ATB) | 14 |
| | Levofloxacin-based triple therapy (PPI + LVFX + AMO) | |

ACG, American College of Gastroenterology; AMO, amoxicillin; ATB, antibiotic; CLA, clarithromycin; MET, metronidazole; P-CAB, potassium-competitive acid blocker (vonoprazan); PPI, proton pump inhibitor; TIN, tinidazole; TET, tetracycline; LVFX, levofloxacin.

pylori, which recommends the use of metronidazole instead of amoxicillin in combination with PPI and clarithromycin in areas with low clarithromycin resistance (less than 15.0%). Currently, clarithromycin resistance rates from five medical schools are ranging between 5.0% - 29.2% (median 13.8%) [3], while metronidazole resistance rates are between 30.0% - 51.9%, both of which are quite high. Therefore, bismuth quadruple therapy may be an appropriate alternative after failure of first treatment with standard triple therapy.

The majority of patients who showed up for their follow-up appointments were tested for UBT, which is a non-invasive test that provides the best accuracy for diagnosis of H. pylori infection. Regarding duration between the first visit and follow-up UBT, this study was close to the recommendations of the 2015 Thai clinical practice guidelines for diagnosing and treating patients with Helicobacter pylori infection [3], which suggests performing UBT to confirm the eradication of H. pylori for at least four weeks after the treatment has ended and at least two weeks after stopping PPI

**Table 4**. Drug regimens for treatment of H. pylori infection, duration of treatment, and eradication rate.[2]

| Regimen | PPI/P-CAB | Antibiotics | Duration of treatment (days) | Eradication rate ITT (%) | Eradication rate PP (%) |
|---|---|---|---|---|---|
| Bismuth quadruple therapy | Lansoprazole (30 mg bid) | MET (500 mg tid) TET (500 mg bid) Bismuth (300 mg bid) | 10 | 74.0 | 93.0 |
| Concomitant quadruple therapy | Esomeprazole (20 mg bid) | AMO (1000 mg bid) CLA (500 mg bid) MET (500 mg bid) | 14 | 87.0 | 94.0 |
| Sequential therapy | Rabeprazole (20 mg bid) | AMO (1000 mg bid) for 5 days, followed by CLA (500 mg bid) for 5 days TIN (500 mg bid) for 5 days | 10 | 82.0 | 95.0 |
| Hybrid therapy | Esomeprazole (40 mg bid) | AMO (1000 mg bid) for 14 days CLA (500 mg bid) for the last 7 days MET (500 mg bid) for the last 7 days | 14 | 83.0 | 95.0 |
| Reverse hybrid therapy | Dexlansoprazole (30 mg bid) | AMO (1000 mg bid) for 14 days CLA (500 mg bid) for the first 7 days MET (500 mg bid) for the first 7 days | 14 | 95.0 | 96.0 |
| PPI-based standard triple therapy | Lansoprazole (30 mg bid) | AMO (1000 mg bid) CLA (500 mg bid) | 14 | 56.0 | 63.0 |
| High-dose PPI-amoxycillin dual therapy | Esomeprazole (20 mg qid) | AMO (750 mg qid) | 14 | 87.0 | 92.0 |
| Vonoprazan-based triple therapy | Vonoprazan (20 mg bid) | AMO (750 mg bid) CLA (200 mg bid) | 7 | 89.0 | 90.0 |
| Vonoprazan-amoxycillin dual therapy | Vonoprazan (20 mg bid) | AMO (750 mg bid) | 7 | 85.0 | 87.0 |

AMO, amoxicillin; bid, twice daily; CLA, clarithromycin; ITT, intention to treat; MET, metronidazole; P-CAB, potassium-competitive acid blocker (vonoprazan); PP, per protocol; PPI, proton pump inhibitor; qd, once daily; qid, 4 times daily; TET, tetracycline; tid, 3 times daily; TIN, tinidazole.

therapy. One of the factors that affected adherence with post-treatment follow-up appointments may be the large number of patients who were waiting to schedule their endoscopy appointments. Regarding the UBT results, if the patient is taking an antibiotic, bismuth, or a PPI, it may generate false negative result. Therefore, antibiotics and bismuth should be stopped for at least four weeks and PPIs for at least two weeks before performing UBT.

The limitation of this study was its retrospective nature, which resulted in incomplete patient information. Additionally, some patients did not come to their follow-up visits. Therefore, further investigations are needed to gather more information.

The main problem found in this study was patients' unawareness of the importance of follow-up visits to confirm eradication of H. pylori after completion of treatment, which may result in patients were still having problems with gastritis and stomach ulcers. Therefore, pharmacists play an important role in giving advice on taking medicine continuously until the treatment period is complete and emphasizing the importance of post-treatment follow-up visits to confirm the elimination of H. pylori and ensure the success of treatment.

## Conclusion

The study found that there were five main drug regimens used for treatment of H. pylori infection at King Chulalongkorn Memorial Hospital, Thai Red Cross Society: standard triple therapy, bismuth quadruple therapy, levofloxacin-based therapy, sequential triple therapy, and vonoprazan-based therapy. There was one patient who was prescribed concomitant therapy after the first treatment had failed. Those regimens provided high eradication rates. Standard triple therapy remained the mainstay of treatment with the usual treatment period of 14 days, which was consistent with the 2015 Thai clinical practice guidelines for diagnosis and treatment of patients with H. pylori infection. Standard triple therapy drug is highly effective with low treatment cost, which makes it accessible to patients. After failure of the first treatment, regimens that doctors prescribed were levofloxacin-based therapy and bismuth quadruple therapy, which also provided effective treatment results.

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## Conflicts of interest statement

All authors have completed and submitted the International Committee of Medical Journal Editors Uniform Disclosure Form for Potential Conflicts of Interest. None of the authors disclose any conflict of interest.

## Data sharing statement

Data sharing statement. All data generated or analyzed during the present study are included in this published article. Further details are available for noncommercial purposes from the corresponding author on reasonable request.

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