HIGH-DOSE AMOXICILLIN FOR *H. PYLORI* GASTRITIS IN CHILDREN: A CASE-SERIES STUDY

Le Thi Thuy Dung[1*], Le Thi Van Anh[2], Nguyen Thi Thanh Thao[1]

[1]*Thu Dau Mot University - 06 Tran Van On, Phu Loi Ward, Ho Chi Minh City, Vietnam*
[2]*Thanh Hoa Pediatric Hospital - 724 Quang Trung Street, Quang Thinh Ward, Thanh Hoa City, Vietnam*

Received: 06/08/2025
Revised: 03/09/2025; Accepted: 19/12/2025

ABSTRACT

Objective: To evaluate the efficacy and safety of a high-dose Amoxicillin regimen in the treatment of gastritis associated with *Helicobacter pylori (H. pylori)* infection in children in Vietnam.

Subjects and methods: A cross-sectional descriptive study was conducted on 50 pediatric patients under 16 years of age (mean age 7.46 ± 3.01 years) diagnosed with first-time *H. pylori-associated* gastritis and treated at Thanh Hoa Pediatric Hospital. The treatment regimen included high-dose Amoxicillin (75-100 mg/kg/day, divided into two doses for 2 weeks) combined with other antibiotics and a proton pump inhibitor (PPI).

Results: After treatment, significant improvements were observed in clinical symptoms: abdominal pain decreased from 100% to 36%, vomiting and nausea from 60% to 8%, belching and acid reflux from 24% to 2%, and bloating and indigestion from 14% to 2%. Minimal adverse events were reported, with abdominal pain in 4% of cases and vomiting or diarrhea in 2%. The eradication rate of *H. pylori* was 44%.

Conclusion: The high-dose Amoxicillin regimen improved clinical symptoms in children with *H. pylori-associated* gastritis. However, the low eradication rate suggests a high prevalence of Amoxicillin resistance in Vietnam. Further studies with larger sample sizes and a control group are needed to identify more effective treatment strategies tailored to local antibiotic resistance patterns.

Keywords: Gastritis, Amoxicillin, *Helicobacter pylori*, treatment outcome, children.

*Corresponding author
Email: dungltt@tdmu.edu.vn **Phone**: (+84) 987008914 **DOI:** 10.52163/yhc.v66i8.3232

1. INTRODUCTION

Gastritis caused by *Helicobacter pylori (H. pylori)* infection accounts for approximately 90% of all gastritis cases. The global prevalence of *H. pylori* infection is estimated to affect around 50% of the population, with significantly higher infection rates observed in developing countries compared to developed nations. The prevalence of *H. pylori* infection in the Vietnamese population is higher than the global average (80%), as reported in Nguyen Cam Tu's study [2]. The eradication of *H. pylori* plays a crucial role in the treatment of *H. pylori associated* gastritis. However, recent studies have shown a significant decline in eradication efficacy due to the increasing prevalence of antibiotic resistance. In Vietnam, multiple studies have reported a rising trend in antibiotic resistance in *H. pylori* eradication therapy over recent years, with resistance rates exceeding 60% [3]. The primary resistance rates to Amoxicillin, Clarithromycin, Metronidazole, Levofloxacin, Tetracycline, and multidrug resistance were 15.0%, 34.1%, 69.4%, 27.9%, 17.9%, and 48.8%, respectively. Meanwhile, the secondary resistance rates for these antibiotics were 9.5%, 74.9%, 61.5%, 45.7%, 23.5%, and 62.3%, respectively [3]. A study conducted on a group of children aged 3 to 15 years in Vietnam reported overall resistance rates to Clarithromycin, Metronidazole, and Amoxicillin of 50.9%, 65.3%, and 0.5%, respectively [3]. Vietnam, like many other countries worldwide, has adopted the standard first-line regimen for *H. pylori* eradication, which consists of a combination of a proton pump inhibitor (PPI) with Clarithromycin and Amoxicillin, or Clarithromycin and Metronidazole, administered for two weeks [3, 5].

Given the increasing resistance of *H. pylori* to Clarithromycin and Metronidazole in pediatric patients, while Amoxicillin resistance remains relatively low, high-dose Amoxicillin therapy has been reconsidered by researchers in various regions for *H. pylori* treatment. According to the 2016 ESPGHAN/NASPGHAN guidelines, Amoxicillin is recommended as the first-line antibiotic regardless of the confirmed resistance status [6]. Amoxicillin combined with a proton pump inhibitor (PPI) has been used in *H. pylori* treatment for a considerable period; however, its actual efficacy has not been clearly established. A study evaluating the eradication efficacy of high-dose Amoxicillin in more than 50% of patients at Children's Hospital No.1 demonstrated that the success rate of *H. pylori* eradication in cases resistant to both Clarithromycin and Metronidazole was 32.6%, which was significantly lower than the eradication rate achieved with standard-dose Amoxicillin (60.6%, p = 0.015) [7].

Vietnam has a high prevalence of multidrug-resistant *H. pylori*, making high-dose Amoxicillin therapy a widely adopted approach for *H. pylori* treatment. However, the effectiveness of this regimen remains controversial. Therefore, we conducted this study to evaluate the efficacy and safety of high-dose Amoxicillin in the treatment of *H. pylori* infection in children in Vietnam.

2. PARTICIPANTS AND METHODS

2.1. Study design

This study employed a cross-sectional case series design, comparing outcomes before and after treatment.

2.2. Study setting and duration: The study was conducted at Thanh Hoa Pediatric Hospital from February to October 2022.

2.3. Study population

The study included 50 patients diagnosed with *H. pylori associated* gastritis who visited Thanh Hoa Pediatric Hospital between February 1, 2022, and October 30, 2022. The diagnosis was confirmed through a rapid urease test and histopathological examination. Gastritis was diagnosed based on endoscopic findings, and *H. pylori* infection was confirmed when two tests were positive: the urease test and histological evidence of H. pylori according to the ESPGHAN/NASPGHAN 2016 criteria.

- Inclusion criteria:

The study included children under 16 years old firstly diagnosed with *Helicobacter pylori-associated gastritis*, treated at Thanh Hoa Pediatric Hospital. All participants were able to comply with the treatment protocol, and adherence was monitored through parental confirmation. Patients being involved must met the criteria of no history of prior antibiotic treatment for the infection within the last 4 weeks. To ensure consistency, only patients who could tolerate the full treatment course and meet the inclusion criteria were selected

- Exclusion criteria: Patients with peptic ulcers, a history of allergy to the selected antibiotics, or those who did not complete the pre- and post-treatment evaluation were excluded. Additionally, patients who did not consent to participate in the study were also excluded.

2.4. Treatment regimen

The treatment regimen for *Helicobacter pylori* eradication involved high-dose Amoxicillin (75-100 mg/kg per day, divided into two doses) for 4 weeks, combined with additional antibiotics such as Metronidazole and Clarithromycin. The regimen was administered alongside a proton pump inhibitor (PPI), following international guidelines with slight modifications based on local resistance patterns.

2.5. Sample size and sampling method: The sample size was determined using a convenience sampling method, including all patients under 16 years old who visited Thanh Hoa Pediatric Hospital between January 2022 and October 2022 and met the inclusion criteria for gastritis diagnosis.

2.6. Study variables

The general characteristics of study participants included age group, gender, medical history, and clinical symptoms such as abdominal pain, vomiting, and diarrhea. Variables related to the treatment included the dosage of Amoxicillin (75-100 mg/kg per day), frequency (twice daily), and the duration of the treatment (four weeks). The study also monitored adverse effects associated with the treatment, such as abdominal pain, nausea, and diarrhea. *H. pylori* status was confirmed through the rapid urease test, urea breath test, or histopathological examination. Two weeks after completing the treatment, the clinical improvement in symptoms and *H. pylori* status were reassessed.

2.7. Data collection techniques, tools, and procedures: The primary data collection tool was a comprehensive clinical assessment conducted by medical staff at Thanh Hoa Pediatric Hospital. This included a thorough medical history review and physical examination of the patients. *H. pylori* infection was confirmed using three diagnostic methods: the rapid urease test, the urea breath test, and histopathological examination. Data on the treatment regimen, including dosage, administration frequency, and duration, were recorded. Adverse effects were monitored throughout the treatment period and documented. The follow-up assessment was conducted two weeks after treatment completion to evaluate clinical improvements and *H. pylori* status. All data were systematically recorded and analyzed to assess the effectiveness and safety of the high-dose Amoxicillin regimen.

2.8. Data processing and analysis: Data collected from study participants were entered and analyzed using SPSS version 22.0. Quantitative variables were expressed as mean ± standard deviation (SD), while categorical variables were reported as frequencies and percentages. Changes in clinical symptoms before and after treatment were assessed using McNemar's test for categorical variables, with statistical significance set at $p < 0.05$. The eradication efficacy of the *H. pylori* treatment regimen was determined based on the proportion of patients with negative post-treatment rapid urease test and histopathological findings, using univariate logistic regression to find the relationship between *H. pylori* eradication and symptoms relief of patients. Adverse events during treatment were also analyzed to evaluate the safety of the regimen.

2.9. Ethical considerations

This study was conducted with the approval and support from the Board of Directors of Thanh Hoa Pediatric Hospital. Informed consent was obtained from the guardians of the pediatric patients before participation. All participants and their family were thoroughly informed about the purpose, procedures, benefits, and responsibilities associated with the study. They were also made aware of their right to voluntarily participate and their right to withdraw from the study at any point without any adverse effects on their ongoing treatment or relationship with the hospital. The confidentiality of all personal and medical information collected during the study was strictly maintained and was used solely for research purposes.

3. RESULTS

During the study period, 50 patients met the inclusion criteria. The average age of the participants was 7.46 ± 3.01 years, ranging from 4 to 16 years. Among them, 68% were in the 5–10-year-old group, 18% were older than 10 years, and the lowest proportion (14%) was in children under 5 years of age. The male-to-female ratio was 1.27:1, with males accounting for 56% and females for 44% of the study population. Regarding treatment efficacy, there was a significant improvement in clinical symptoms after four weeks of treatment (Figure 1).

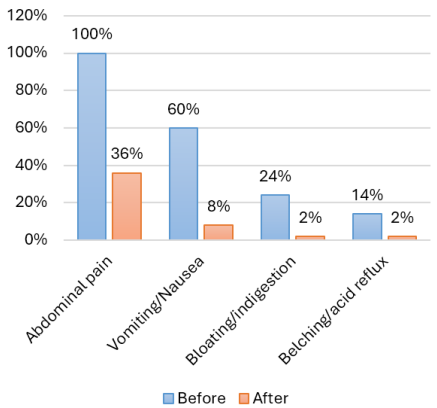

Figure 1. Comparison of symptom changes before and after treatment

The evaluation of *H. pylori* eradication efficacy revealed that 44% of the children had no detectable *H. pylori* following treatment (Figure 2). Table 1 illustrates the correlation between *H. pylori* eradication and symptom resolution. The eradication success rate was 44%, with 86.4% of these patients experiencing symptom resolution. In contrast, among those with persistent *H. pylori* infection (56%), only 39.3% had symptom improvement. The p-value (0.01) indicates a statistically significant association between eradication and symptom relief. The odds ratio (OR = 2.20, 95% CI: 1.35–3.59) suggests that patients with *H. pylori* eradication were 2.2 times more likely to achieve symptom resolution.

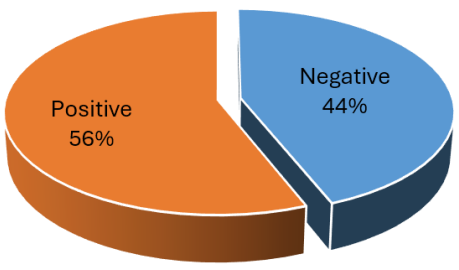

Figure 2. *H. pylori* eradication efficacy

Table 1. Relationship between symptoms and *H. pylori* eradication outcomes using the high-dose Amoxicillin Regimen

Urea breath test	Clinical symptoms after treatment				Total		p	OR
	Resolved symptoms		Persistent symptoms					
	n	%	n	%	n	%		
Negative	19	86.4%	3	13.6%	22	44%	0.01	2.20 95% CI (1.35-3.59)
Positive	11	39.3%	17	60.7%	28	66%		
Total	30	60%	20	40%	50	100%		

Table 2. Adverse effect of *H. pylori* eradication using the high-dose Amoxicillin Regimen

Adverse effects	n	%
Abdominal pain	2	4.0
Vomiting	1	2.0
Diarrhea	1	2.0
Others	0	0
Total	4/50	8

4. DISCUSSION

Our study was conducted on 50 children diagnosed with Helicobacter pylori (H. pylori)-associated peptic ulcer disease who met the inclusion criteria. The average age of the patients was 7.46 ± 3.01 years, ranging from 4 to 16 years. Among them, the highest proportion (68%) belonged to the 5–10-year-old group, followed by 18% in children older than 10 years, and 14% in those younger than 5 years. These proportions are consistent with the findings of TLN Chau's 2018 study, in which the average age of pediatric patients was 7.26 ± 2.2 years, with 86.5% in the 5–10-year-old group, 10.3% in those older than 10 years, and only 3.2% in children younger than 5 years. Our study also found no significant difference in disease prevalence between genders, with 28 males (56%) and 22 females (44%), corresponding to a male-to-female ratio of 1.27:1. This ratio is similar to that reported in TLN Chau's study, where the male-to-female ratio was 1.17:1 [1].

The efficacy of the high-dose Amoxicillin regimen in *H. pylori* eradication (Figure 2) was evaluated in our study involving 50 pediatric patients. The eradication success rate was 44%. This outcome is comparable to findings from previous studies, including TLN Chau's 2018 research, which reported success rates of 48% without bismuth and 86% with bismuth supplementation, as well as HV Thieu's study, which documented a success rate of 34.1% [1, 7]. This can be explained by the high prevalence of Amoxicillin resistance in Vietnam. The results from Table 1 indicate that the group of children in whom *H. pylori* eradication was successful exhibited a greater reduction in clinical symptoms compared to those in whom the bacteria persisted. This finding underscores the critical role of *H. pylori* eradication in the treatment of gastritis, a fact consistently supported by numerous previous studies. Furthermore, the incorporation of probiotics into *H. pylori* eradication regimens warrants consideration. Probiotics have been shown to contribute to eradication by producing antimicrobial and antioxidant compounds, as well as by locally altering gastric pH, thereby reducing bacterial invasion and adhesion to gastric epithelial cells. It is important to note, however, that while beneficial, probiotics primarily serve as an adjunctive therapy, as their standalone use does not significantly enhance eradication efficacy [8,9].

In assessing the clinical response, our study observed a significant improvement in symptoms following treatment. The proportion of children experiencing abdominal pain decreased from 100% to 36%, a result comparable to TLN Chau's study, where the rate declined from 97.5% to 31.7%. Similarly, the incidence of nausea and vomiting was reduced from 60% to 8%, consistent with TLN Chau's findings (48.4% to 4.8%) [1]. Other symptoms, such as belching and acid reflux, decreased from 24% to 2%, while bloating and indigestion were reduced from 14% to 2%. In our study, *H. pylori* eradication had a positive impact on clinical symptom improvement, with patients who successfully eradicated *H. pylori* being 2.2 times more likely to achieve symptom resolution compared to those in whom eradication failed (95% CI: 1.347–3.587, p = 0.01). Similarly, a study conducted in Turkey demonstrated an improvement in dyspepsia symptom scores in the group with successful *H. pylori* eradication [10]. This finding reinforces the future significance of *H. pylori* treatment in the management of peptic ulcer disease.

Regarding the safety profile of the regimen, our study recorded a very low incidence of adverse effects. Only 4% of patients experienced mild abdominal pain during treatment, while nausea and diarrhea were observed in

just 2% of cases. This excellent tolerability represents a significant advantage of the high-dose Amoxicillin regimen. Indeed, while traditional *H. pylori* eradication regimens, particularly those containing Clarithromycin or Metronidazole, are frequently associated with a higher frequency of adverse events, including gastrointestinal disturbances and taste alteration, leading to reduced patient compliance [11, 12], our findings suggest a more favorable safety profile with high-dose Amoxicillin. This superior tolerability is crucial, especially in pediatric patients, where adverse effects can significantly impact adherence to the treatment course [12].

This study has several limitations. First, the absence of a control group makes it challenging to accurately assess the effectiveness of the high-dose Amoxicillin protocol in isolation. Second, the lack of subgroup analysis based on disease severity limits the ability to evaluate treatment efficacy at different stages of the condition. Additionally, potential confounding factors such as diet, lifestyle, and underlying medical conditions were not controlled, which may affect the interpretation of the results. The follow-up period of only two weeks does not allow for the assessment of long-term outcomes, including *H. pylori* reinfection. Furthermore, a comprehensive evaluation of long-term side effects is necessary. Addressing these factors in future studies will provide a more thorough understanding of the treatment's effectiveness and safety.

5. CONCLUSION

The high-dose Amoxicillin regimen for *H. pylori* treatment achieved an eradication rate of 44%, indicating a relatively low success rate compared to international studies. However, this regimen still demonstrated significant clinical symptom improvement in patients with successful *H. pylori* eradication. Additionally, it has the advantages of minimal side effects and ease of administration, enhancing patient adherence to treatment. Nevertheless, given the increasing prevalence of Amoxicillin resistance in Vietnam, further large-scale studies are needed to comprehensively evaluate the efficacy and long-term sustainability of this regimen. Long-term follow-up and the incorporation of adjunctive treatment strategies, such as bismuth-based therapy or alternative antibiotics, may enhance the effectiveness of *H. pylori* eradication in the future.

FUNDING

This study was not funded by grants.

ACKNOWLEDGEMENT

The authors would like to express their sincere gratitude to Thu Dau Mot University and Thanh Hoa Pediatric Hospital for their invaluable support in the data collection process for this study.

REFERENCES

[1] Tăng Lê Châu Ngọc. Đặc điểm đề kháng kháng sinh và đáp ứng điều trị trên trẻ viêm dạ dày do Helicobacter pylori. Luận văn chuyên khoa cấp II. Trường Đại học Y Dược Thành phố Hồ Chí Minh, 2018.

[2] Nguyen TC, Tang NLC, Le GKN, Nguyen VT, Nguyen KHG, Che TH, Phan VTT, Nguyen NM, Truong DQ, Ngo XM, Nguyen HT, Robert A, Bontems P, Nguyen PNV. Helicobacter pylori Infection and Peptic Ulcer Disease in Symptomatic Children in Southern Vietnam: A Prospective Multicenter Study. Healthcare (Basel). 2023 Jun 5;11(11):1658. doi: 10.3390/healthcare11111658. PMID: 37297795; PMCID: PMC10253129.

[3] V. V. Khien, D. M. Thang, T. M. Hai, N. Q. Duat, P. H. Khanh, D. T. Ha, T. T. Binh, H. D. Q. Dung, T. T. H. Trang, Y. Yamaoka, "Management of Antibiotic-Resistant Helicobacter pylori Infection: Perspectives from Vietnam", Gut Liver, 13 (5): 483-497, 2019.

[4] T. V. Nguyen, C. Bengtsson, L. Yin, G. K. Nguyen, T. T. Hoang, D. C. Phung, M. Sörberg, M. Granström, "Eradication of Helicobacter pylori in children in Vietnam in relation to antibiotic resistance", Helicobacter, 17 (4): 319-25, 2012.

[5] T. U. Wheeldon, M. Granström, T. T. Hoang, D. C. Phuncarg, L. E. Nilsson, M. Sörberg, "The importance of the level of metronidazole resistance for the success of Helicobacter pylori eradication", Aliment Pharmacol Ther, 19:1315–1321, 2004.

[6] N. L. Jones, S. Koletzko, K. Goodman, P. Bontems, S. Cadranel, T. Casswall, S. Czinn, B. D. Gold, J. Guarner, Y. Elitsur, M. Homan, N. Kalach, M. Kori, A. Madrazo, F. Megraud, A. Papadopoulou, M. Rowland; ESPGHAN, NASPGHAN, "Joint ESPGHAN/NASPGHAN Guidelines for the Management of Helicobacter pylori in Children and Adolescents (Update 2016)", J Pediatr Gastroenterol Nutr., 64 (6): 991-1003, 2017.

[7] H. V. Thieu, N. M. Duc, B. T. D. Nghi, N. V. Bach, H. H. Khoi, V. N. T. Tien, M. T. L. Bang, T. L. C. Ngoc, "Antimicrobial Resistance and the Successful Eradication of Helicobacter pylori-Induced Gastroduodenal Ulcers in Vietnamese Children", Med Arch, 75(2):112-115, 2021.

[8] Meliț LE, Mărginean CO, Săsăran MO. The Challenges of Eradicating Pediatric Helicobacter pylori Infection in the Era of Probiotics. Children (Basel). 2022;9(6):795. Published 2022 May 28. doi:10.3390/children9060795

[9] Chakravarty K, Gaur S. Role of Probiotics in Prophylaxis of Helicobacter pylori Infection. Curr Pharm Biotechnol. 2019;20(2):137-145. doi: 10.2174/1389201020666190227203107. PMID: 30827235.

[10] Ünlüsoy Aksu A, Yılmaz G, Eğritaş Gürkan Ö, Sarı S, Dalgıç B. The effect of Helicobacter pylori eradication on functional dyspepsia in Turkish children. Helicobacter. 2018 Aug;23(4):e12497. doi: 10.1111/hel.12497. Epub 2018 Jun 6. PMID:

29873438.

[11] Nyssen OP, Perez-Aisa A, Tepes B et al. Adverse Event Profile During the Treatment of Helicobacter pylori: A Real-World Experience of 22,000 Patients From the European Registry on H. pylori Management (Hp-EuReg). Am J Gastroenterol. 2021 Jun 1;116(6):1220-1229. doi: 10.14309/ajg.0000000000001246. PMID: 33840725.

[12] Manfredi M, Gargano G, Gismondi P, Ferrari B, Iuliano S. Therapeutic eradication choices in Helicobacter pylori infection in children. Therap Adv Gastroenterol. 2023;16:17562848231170052. Published 2023 Apr 27. doi:10.1177/17562848231170052