



# Impact of Clinical Pharmacist-led Intervention on Clinical Outcomes in Patients with *Helicobacter pylori* Infection

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## Abstract

**Background and objectives:** *Helicobacter pylori* infection is prevalent and persistent in some cases. The rising incidence of drug resistance in this infection necessitates enhanced treatment methodologies. Our aim was to compare the efficacy of conventional therapy with that of a clinical pharmacist-led intervention for the management of *Helicobacter pylori* infection.

**Methods:** This randomized controlled trial included 100 therapy-naïve patients with confirmed *Helicobacter pylori* infection, recruited from an outpatient private clinic in Koye-Erbil, Iraq, between May and November 2023. Patients were randomly assigned to either the control group (receiving conventional therapy) or the intervention group (receiving additional clinical pharmacist-led interventions focused on personalized treatment plans, patient education, and adherence support). Treatment success was assessed using the *Helicobacter pylori* stool antigen test for follow up one-month post-treatment. Medication compliance was evaluated using the Morisky-Green scale.

**Results:** In this study, 54 (54.0) patients were female and 46 (46.0) patients were male. The intervention group showed a significantly higher rate of *H. pylori* eradication, with 42 (84%) patients testing negative in the second stool antigen test compared with 28 (56%) patients in the control group ( $p \leq 0.002$ ). Furthermore, medication compliance was significantly better in the intervention group of 36 (72%) patients compared to the control group of 18 (29%) patients ( $p < 0.013$ ).

**Conclusion:** Clinical pharmacist interventions improve therapeutic outcomes and medication compliance in patients with *Helicobacter pylori* infection. Although integrating into peptic ulcer disease management teams enhances the treatment effectiveness.

**Keywords:** Clinical pharmacist intervention, Controlled trial, *Helicobacter pylori* infection, Medication adherence

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## Introduction

*Helicobacter pylori* (*H. pylori*) is a common infection and often persists for a lifetime.<sup>1</sup> This infection, caused by gram-negative bacteria that colonize the stomach lining.<sup>2</sup> Over the past three decades, the prevalence of *H. Pylori* infections has increased due to population growth, reinfection, and recrudescence associated with eradication failures.<sup>3</sup> Clinical pharmacists have recognized that pharmacist-managed services can optimize *Helicobacter pylori* treatment in collaboration with gastroenterologists.<sup>4</sup> Nevertheless, as living standards improve, the incidence of *H. pylori* infection is declining in many countries.<sup>5</sup> Although the frequency of the disease varies by region, it affects over a million people globally.<sup>6</sup> Risk factors for *Helicobacter pylori* infection and its transmission include socioeconomic advancements, residing in unhygienic and crowded environments, and increased prevalence with age.<sup>7</sup> Iatrogenic infection can also occur during endoscopic procedures, while family transmission remains the primary route of disease propagation.<sup>8,9</sup> In addition to causing persistent mucosal inflammation, *Helicobacter pylori* infection has been linked to stomach malignancies and chronic gastritis.<sup>7,8,10</sup> Successfully eliminating the *H. pylori* infection can reduce the incidence of duodenal or gastric ulcer disease and non-ulcer dyspepsia, which have been directly associated with a reduced risk of *H. pylori* infection.<sup>11</sup> However, most individuals with *H. pylori* infections do not experience significant clinical complications.<sup>7</sup> Several noninvasive strategies are available for both the diagnosis and follow-up of *H. pylori* treatment, including urea breath testing, stool antigen testing, and serologic testing, which are recommended for younger patients with upper gastrointestinal symptoms but no warning signs (abdominal mass, anemia, rectal bleeding and weight loss).<sup>7</sup> Invasive

tests include direct detection of *H. pylori* on biopsy samples obtained during endoscopy.<sup>8</sup> Antibiotics, proton-pump inhibitors (PPIs), and bismuth salts are among the drug regimens used to treat *H. pylori* infection.<sup>10</sup> A month after the end of antibiotic treatment, it is necessary to check for infection clearance using a stool antigen test or urea breath test.<sup>8</sup> In clinical trials, the eradication rate of *H. pylori* varies from 70% to 90%. The complexity of multiple treatment regimens, underlying antibiotic resistance, pill burden, and prescribing and administration errors, however, may contribute to decreased eradication rates.<sup>12-14</sup> Medication counseling and adherence treatments can be integrated into pharmacists' engagement in *H. pylori* infection.<sup>4, 15, 16</sup> Throughout the course of treatment, a clinical pharmacist can educate the patient.<sup>4, 16</sup> In a study where pharmacists assessed the suitability of *H. pylori* treatment through patient education, counseling, and telephone follow-up, 100% of patients adhered to the therapy with minimal side effects and no notable drug interactions.<sup>17</sup> The eradication rate and the patient's quality of life are both enhanced by the clinical pharmacist's medication advice. From a pharmacoeconomic perspective, pharmacist-run clinics are also advantageous.<sup>16</sup> Due to the increase in reported cases of drug resistance and eradication failures, improving treatment strategies and methods is necessary.<sup>18, 19</sup> This background prompts the question: Can pharmaceutical intervention care play a role in improving the therapeutic outcome in peptic ulcer patients? Therefore, this study aimed to assess and compare the effectiveness of conventional therapy alone and a combined approach involving clinical pharmacist-led disease management in treating individuals diagnosed with *H. pylori* infection.

## Patients and methods

This study included 100 patients (46 men and 54 women) diagnosed with *H. pylori*





infection. These individuals sought treatment at a private outpatient clinic in Koye-Erbil, Iraq, between May 15, 2023, and November 15, 2023. The inclusion criteria were patients who were therapy-naïve and had a positive stool *H. pylori* antigen test. Participants who had been previously treated for *H. pylori* and were known to be hypersensitive to medications or had taken both PPIs and antibiotics in the two weeks before the study were excluded. This study was structured as a randomized controlled trial. Eligible patients were equally divided into two groups: the control group (CG) received standard therapy, while the intervention group (IG) received standard therapy supplemented by clinical pharmacist-led interventions. The interventions involved tailoring the treatment to individual parameters such as age, sex, comorbidities, and hypersensitivity; educating patients about drug toxicity, side effects, and allergic reactions; identifying potential drug-related issues such as dosage, duration, frequency, and form; and educating patients on the importance of treatment adherence to prevent complications. Furthermore, patients in the IG received additional support to improve medication adherence, such as tele-messages or mobile contacts, mobile alarms, and pill counters. For both patient groups, the Morisky-Green (MG) scale was used to evaluate drug compliance. There were four questions on this scale: Question B1) Have you ever forgotten your prescription? Question B2) Have you ever ignored a doctor's direction when taking your medication? Question B3) Have you stopped taking your medication because your symptoms have subsided or are you not experiencing any noticeable symptoms? (Question B4): Due to worsening symptoms or unfavorable reactions, have you stopped taking your medication? "No" was worth one point, and "yes" was worth zero.<sup>26</sup> The efficacy of the treatment was measured using

the *H. pylori* stool antigen test conducted before and one-month post-treatment to confirm bacterial eradication. Statistical analysis was performed using the SPSS software, version 21. Both the mean and standard deviation are descriptive statistics included in the statistical analysis. To compare the first antigen test (FAT) results between the two groups, the chi-square and Fisher exact tests were employed. Statistical significance was set at  $p < 0.05$ . The study was approved by the Ethics Committee of the Kurdistan Higher Council of Medical Specialties (Approval No. 976, dated May 14, 2023). All participants provided written informed consent after receiving a comprehensive description of treatment options. The researcher explained the study's objectives to the participants, ensuring the confidentiality and anonymity of their data and affirming their right to withdraw from the study at any point.

## Results

Table (1) displays the differences in the demographic characteristics between the control and IG s. The sex distribution in the CG comprised 29 (58.0%) females and 21 (42.0%) males, while the IG had an equal number of male and female participants. Statistical analysis confirmed no significant differences in the sex distribution between the two groups. Similarly, the age distribution revealed that 31 (62.0%) patients in the CG and 37 (74.0%) in the IG were aged between 19-45 years, with 11 (22.0%) and 7 (14.0%) aged between 45-65 years, respectively, showing no significant difference between the groups. Comparisons of smoking status indicated 39 (78.0%) non-smokers in the CG and 37 (74.0%) in the IG, with no discernible differences identified. The majority of patients in both groups were married, comprising 36 (72.0%) in the CG and 39 (78.0%) in the IG, with no significant variation. No statistically significant differences were observed in residential





locations. However, literacy levels differed significantly: 25 (50.0%) patients in the CG and 21 (42.0%) in the IG had primary-level literacy, whereas 19 (38.0%) in the CG and 11 (22.0%) in the IG were illiterate ( $p \leq 0.008$ ). The history of NSAID usage also exhibited notable disparities, with 44 (88.0%)

patients in the CG and 50 (100.0%) in the IG reporting no prior NSAID use ( $p < 0.027$ ). The drug sensitivity history showed that 49 (98.0%) patients in the CG and 50 (100.0%) in the IG reported no history, and there was no significant difference.

**Table (1):** Socio-demographic characteristics of both groups

Socio demographics variable		Group (No, %)		Total	p value*
		Control (n= 50)	Intervention (n= 50)		
Gender	Female	29(58.0)	25(50.0)	54(54.0)	0.422
	Male	21(42.0)	25(50.0)	46(46.0)	
Age group	13 – 18 Youth	3(6.0)	5(10.0)	8(8.0)	0.226
	19 – 45 early adults	31 (62.0)	37(74.0)	68(68.0)	
	46 – 65 mature adults	11(22.0)	7(14.0)	18(18.0)	
	≥ 66 Elderly	5(10.0)	1(2.0)	6(6.0)	
Smoking	Non-smoker	39(78.0)	37(74.0)	76(76.0)	0.64
	Smoker	11(22.0)	13(26.0)	24(24.0)	
Marital status	Single	14(28.0)	11(22.0)	25(25.0)	0.488
	Married	36(72.0)	39(78.0)	75(75.0)	
Address	Urban	28(56.0)	22(44.0)	50(50.0)	0.230
	Residence	22(44.0)	28(56.0)	50(50.0)	
Level of education	Illiterate	19(38.0)	11(22.0)	30(30.0)	0.008
	Primary level	25(50.0)	21(42.0)	46(46.0)	
	Secondary level	5(10.0)	6(12.0)	11(11.0)	
	Institute and college	1(2.0)	12(24.0)	13(13.0)	
NSAIDs	No	44(88.0)	50(100.0)	94(94.0)	0.027
	Yes	6(12.0)	0(0.0)	6(6.0)	
Drug allergy	No	49(98.0)	50(100.0)	99(99.0)	1.000
	Yes	1(2.0)	0(0.0)	1(1.0)	
Drinking alcohol	No	47(94.0)	49(98.0)	96(96.0)	0.617
	Yes	3(6.0)	1(2.0)	4(4.0)	

\* P-value chi-square



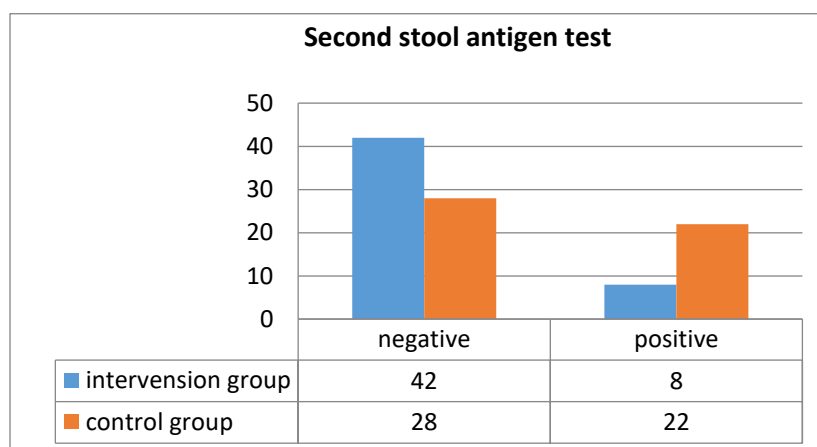
There were no statistically significant differences in the presence of comorbidities (hypertension, diabetes, hypo- and hyperthyroidism, obesity, anemia, BPH (Benign Prostatic Hyperplasia), and COPD (Chronic Obstructive Pulmonary Disease) between the groups. The difference in the results of the second FAT was significant

between the Control and IGs ( $p \leq 0.002$ ) Table (2). Only 8 (16%) patients had a positive test result in the IG, while 42 (84%) patients had negative test results. However, in the CG, 28 (56%) patients had negative results, while 22 (44%) had positive results Figure (1).

**Table (2):** Clinical characteristics in participations according groups Control and Intervention

Clinical characteristics		Group (No, %)		Total	p value*
		Control	Intervention		
Comorbidity	None	37(74.0)	44(88.0)	81(81.0)	0.124
	Polycystic ovary syndrome	1(2.0)	0(0.0)	1(1.0)	
	ANEMIA	1(2.0)	0(0.0)	1(1.0)	
	HYPERTENSION	5(10.0)	1(2.0)	6(6.0)	
	HYPOTHYROIDISM	0(0.0)	1(2.0)	1(1.0)	
	DIABETIC	2(4.0)	3(6.0)	5(5.0)	
	OBSESITY	1(2.0)	0(0.0)	1(1.0)	
	HYPERTHYROIDISM	2(4.0)	0(0.0)	2(2.0)	
	Benign prostatic hyperplasia	1(2.0)	0(0.0)	1(1.0)	
	COPD	0(0.0)	1(2.0)	99(99.0)	
Antibiotics	No	49(98.0)	49(98.0)	98(98.0)	1.000
	Yes	1(2.0)	1(2.0)	2(2.0)	
Herbal medication	No	48(96.0)	50(100.0)	98(98.0)	0.495
	Yes	2(4.0)	0(0.0)	2(2.0)	
Family history of Peptic Ulcer	No	24(48.0)	17(34.0)	41(41.0)	0.155
	Yes	26(52.0)	33(66.0)	59(59.0)	
patient compliance	No	32(70.0)	14(30.0)	45(45.0)	0.013
	Yes	18(36.0)	36(64.0)	55(55.0)	
Second FAT	Negative	28(56.0)	42(84.0)	70(70.0)	0.002
	Positive	22(44.0)	8(16.0)	30(30.0)	

\* $p$ -value fisher exact test

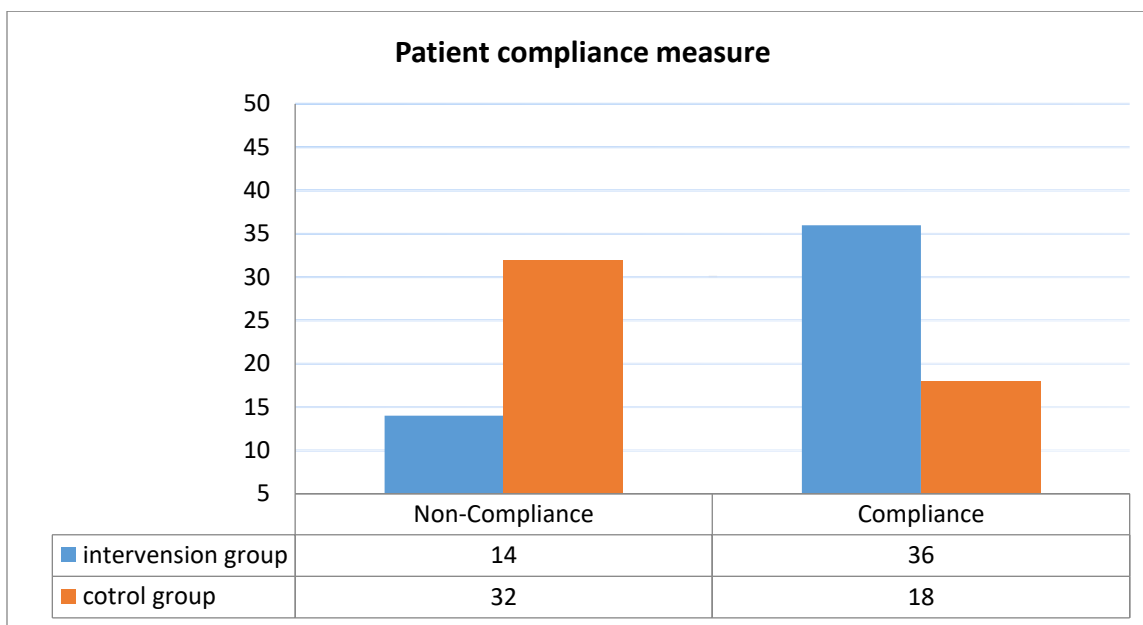


**Figure (1):** Effects of the pharmacy-led intervention on the therapeutic outcomes of the control and IGs.



Medication compliance was significantly higher in the IG than in the CG ( $p < 0.013$ ) Table (2) and Figure (2). In the IG, 36

(72.0%) patients were compliant with their medication regimen, whereas only 18 (29.0%) patients in the CG were compliant.



**Figure (2):** The effects of pharmacy-led intervention on patient compliance.

## Discussion

Numerous studies indicate that nearly half of the global population carries *H. pylori* infections, prompting health systems worldwide to update guidelines and enhance programs aimed at reducing transmission and increasing eradication rates.<sup>14,20,21</sup> Growing evidence supports the role of clinical pharmacists in healthcare, demonstrating their positive impact on clinical outcomes and patient health status.<sup>22</sup> This study aimed to assess the effect of clinical pharmacist interventions on the treatment of *H. pylori* infection. Patients who received pharmacist interventions exhibited markedly higher medication compliance than those in the CG. This improvement can be attributed to pharmacists' role in optimizing treatment managements based on individual patient conditions, thereby minimizing the risk of side effects and drug interactions. Moreover, patient education on the disease and the importance of completing treatment courses

to prevent complications significantly contribute to an improved quality of life. Research investigating the impact of pharmacist follow-up and consultation has revealed that patients managed under pharmacist care demonstrate better adherence to prescriptions and more successful *H. pylori* eradication.<sup>23</sup> Additional studies focusing on the role of pharmacists in improving *Pylori* treatment processes have shown that interventions in drug selection, patient education, and addressing drug-related issues lead to more effective disease management and outcomes.<sup>17,22</sup> This effectiveness is evidenced by a retrospective cohort study where pharmacists provided treatment planning, patient education, and monitoring, leading to a high success rate in patient treatment outcomes.<sup>4</sup> One of the important aspects of clinical pharmacist interventions that can affect the results of interventions is patient compliance with medication.<sup>17,24</sup> Patients who adhere to their







medication regimens tend to show greater commitment and confidence in managing their health, overcoming common barriers to compliance through targeted education.<sup>25</sup> A study conducted by Weng et al. identified medication compliance as a key success factor for treatment outcomes.<sup>26</sup> Pharmacist interventions have similarly influenced treatment processes and outcomes in other medical fields, including liver and biliary surgery, digestive system diseases, intensive care management, and drug abuse.<sup>27-30</sup> These interventions have proven effective in enhancing treatment adherence, providing education, conducting follow-ups, and managing adverse effects. One limitation of this study was the low medication usage because of socioeconomic factor among some patients, suggesting that future research should investigate strategies to address this issue.

## Conclusion

Clinical pharmacist-led interventions for treating patients diagnosed with *H. pylori* infection can significantly improve therapeutic outcomes by enhancing patient adherence to treatment regimens. This study strongly supports the integration of clinical pharmacists into the management of peptic ulcer disease.

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## Declaration of conflict of interest:

There are no conflicts of interest among the writers.

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