



A Prospective study on Symptomatic Improvement of Helicobacter pylori Positive patients taking Standard Triple Therapy: A Pilot study

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Abstract

Background: The symptomatic improvement of Helicobacter pylori (H.pylori) infection can be achieved using standard triple therapy. Recently eradication rate of the regimen has declined and this study to find evidence how beneficially the symptoms can be reduced by the 14 day therapy.

Aim: To assess the symptomatic betterment from standard triple therapy.

Methods: Fifteen patients diagnosed with H.pylori infection were recruited for the study. They were administered with standard triple therapy for 14 day course. The regimen consists of Proton pump inhibitor (40 mg b.i.d), Amoxicillin (1000mg), Clarithromycin 500mg b.i.d).The symptoms were assessed using Gastrointestinal Symptom Rating Scale (GSRS) questionnaire. Patients completed GSRS questionnaire during the first week of treatment and after the completion of treatment.

Results: A total of 15 patients with RUT (Rapid Urease Test) positive for H.pylori were treated with standard triple therapy for 14 days. No patients were excluded due to an incomplete questionnaire. The overall symptom reduction after successful completion of therapy is 71.75%. In terms of five major symptom patterns like abdominal pain score, reflux score, indigestion score, diarrhoea and constipation score were also found to be reduced significantly.

Conclusion: Significant reduction in symptoms with H.pylori infection were seen in patients those complete the standard 14 day triple therapy. Patients were found to be symptomatically improved.

Keywords: Symptomatic improvement, Helicobacter pylori infection, Standard triple therapy, 14 day course, GSRS.

Introduction

Helicobacter pylori (H. pylori) is spiral in shape with a flagellum, gram-negative, micro aerophilic bacterium which colonizes in the human gastric mucosa. H. pylori infection can ultimately result in

many serious complications such as peptic ulcer disease (gastric and duodenal), chronic gastritis, gastric cancer and gastric mucosal-associated lymphoid tissue lymphoma.⁽¹⁾

H. pylori can also cause metabolic dysfunctions like insulin resistance, increase in low density

lipoprotein cholesterol and a decrease in high density lipoprotein cholesterol.⁽²⁾

The main mechanisms of symptom development in *H. pylori*-associated peptic ulcer disease were altered GI motility and mucosal inflammation and chronic gastritis. Decreased gastric acid secretion could also result in dysbiosis of gut microflora.⁽³⁾ *H.pylori* eradication could result in symptom improvement.

Although a variety of regimens are available for the eradication of *H. pylori*, the American College of Gastroenterology still recommends the use of Standard Triple Therapy. The standard triple therapy consisting of Proton Pump Inhibitor, Amoxicillin and Clarithromycin is still recommended as one of the first line anti-*H. pylori* treatments when the resistance rate of *H. pylori* to clarithromycin is less than 15%-20%.⁽⁴⁾

Even though there has been several studies to determine the eradication rate there is only few studies regarding the symptomatic improvement after *H. pylori* eradication.⁽⁵⁻⁷⁾ So the study aims to assess the therapeutic gain and relief of symptoms in *H.pylori* positive patients taking standard triple therapy.

Methods

In total 15 patients who visited the department of gastroenterology at a territory care hospital with abdominal symptom as their chief complaint in whom upper GI endoscopy is done; which reveal gastric erosion and erythema. Rapid urease test was carried out and Helicobacter pylori positive patients was recruited for this study.

Inclusion Criteria

- 1) Patients on standard Triple therapy for Helicobacter pylori.
- 2) Patients of age greater than 18years.
- 3) Patients with positive rapid urease test(RUT).

Exclusion Criteria

- 1) Patients with previous history of Helicobacter pylori eradication.
- 2) Patients with hepatic and renal impairment.
- 3) Pregnant and lactating women.

4) Patients on prolonged Proton pump inhibitors, Antibiotics therapy, Anticoagulants and NSAIDS.

5) Patients had a history of allergy or hypersensitivity to any antibiotics in the regimen.

Standard triple therapy regimen for the eradication of helicobacter pylori was administered for 14 days (Proton Pump Inhibitor 40mg b.i.d, Amoxicillin 1000mg b.i.d, Clarithromycin 500mg b.i.d).⁽⁸⁻⁹⁾ In the beginning of study Informed consent was obtained from the patients.

The symptomatic betterment was assessed using Gastrointestinal Symptom Rating Scale (GSRS) questionnaire.⁽¹⁰⁻¹²⁾ The GSRS questionnaire was given twice to the patient. Initially the questionnaire was given before the administration of the regimen. After the completion of 14 day therapy, the patients were instructed to complete the GSRS questionnaire for the second time and the scores were assessed before and after the treatment.

Statistical Analysis

Data were presented as the mean \pm SE. Differences between continuous variables were analyzed using paired t test. In all test, a P value of < 0.05 was considered to be significant.

Result

A total of 15 *H.pylori* positive patients were treated with Standard triple therapy. No patients were excluded due to an incomplete questionnaire. None of the patients had ever undergone *H. Pylori* eradication therapy before entering into this study. None of the 15 patients had taken NSAIDS, antibiotics, and proton pump inhibitors within 1 month prior to entry into this study.

The age of the 15 patients range from 18-85 years .From table 1 it is seen that 26.7% belongs to age group 18-40 and 40-60.

46.6% belongs to age group 60-80.From our study; most of the patients belonged to age group of 60-80.

Table 1 Age of the patients

Age	Frequency	Percent
18-40	4	26.7
40-60	4	26.7
60-80	7	46.7
>80	0	0
Total	15	100

From table 2 it is seen that male patients (60%) are at increased risk of getting infected with H. Pylori than female patients (40%).

Table 2 Gender distribution of the patients

Sex	Frequency	Percent
Male	9	60
Female	6	40
Total	15	100

From the table 3; paired t test showed that there is highly significant effect of treatment in improving overall betterment of symptoms ($P < 0.01$). Before treatment the patient reported an average overall symptom score of 4.0000 ± 0.23 and after treatment the score significantly reduced to 1.13 ± 0.09 ; thus the overall symptom reduction after the successful eradication of H.pylori is 71.75%.

Table 3 Mean score of GSRS before and after treatment

Symptom score		Mean	SD	SE(Mean)
Overall symptom score	Before	4.0000	0.92582	0.23905
	After	1.1333	0.35187	0.09085
Reflux score	Before	3.4000	1.80476	0.46599
	After	1.1333	0.35187	0.09085
Abdominal pain score	Before	4.4667	1.5522	0.40079
	After	1.2000	0.41404	0.10690
Indigestion score	Before	4.4000	1.50238	0.38791
	After	1.0667	0.25820	0.06667
Diarrhoea score	Before	4.5333	2.0307	0.52433
	After	1.1333	0.35187	0.09085
Constipation score	Before	2.7333	1.38701	0.35813
	After	1.2000	0.41404	0.10690

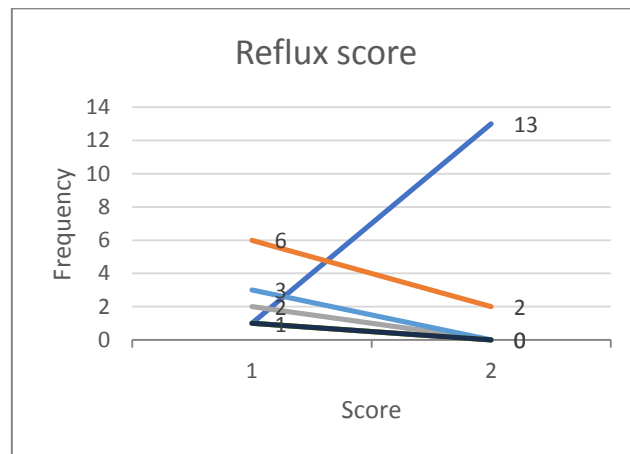


Figure 1 Reflux score in GSRS before and after treatment

In terms of the five major symptom patterns, the scores for reflux symptoms (Figure 1) tend to be decreased after the successful eradication of H.pylori (before eradication: 3.4 ± 0.46 ; after eradication 1.1 ± 0.09). The reflux symptoms was assessed based on the questions related to heart burn and acid reflux. The scores for abdominal pain (Figure2) were significantly decreased (before eradication: 4.46 ± 0.4 ; after eradication 1.2 ± 0.10). The abdominal pain score was highest and was assessed with the questions related to upper abdominal pain and hunger pain. After the completion of standard triple therapy there is a significant symptomatic betterment.

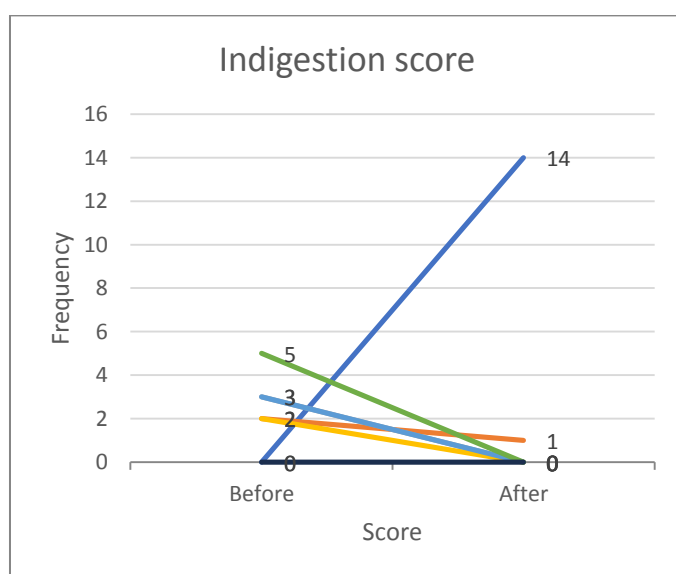


Figure 3 Indigestion score in GSRS before and after treatment

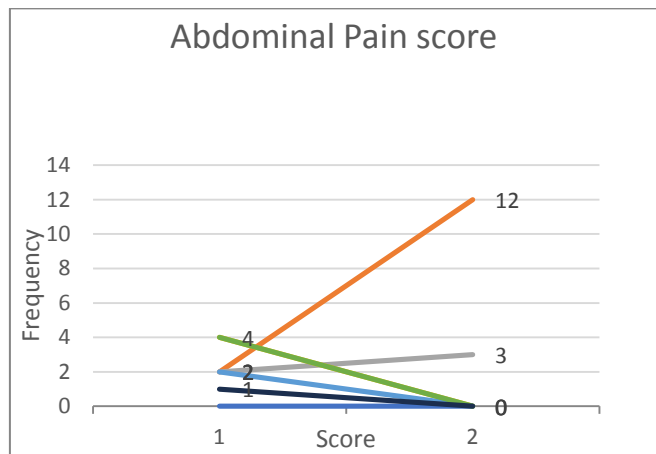


Figure 2 Abdominal pain score in GSRS before and after treatment

After the completion of therapy the indigestion score (Figure 3) also seemed to be reduced (before treatment 4.4 ± 0.3 ; after treatment 1.06 ± 0.06). The indigestion score was assessed with the questions related to abdominal rumbling, bloating, burping and flatulence. Diarrhoea score (Figure 4) reduced significantly (before treatment 4.5333 ± 0.524 ; after treatment 1.133 ± 0.09). Similarly the constipation score (Figure 5) has also decreased (before treatment 2.733 ± 0.358 ; after treatment 1.2 ± 1.06)

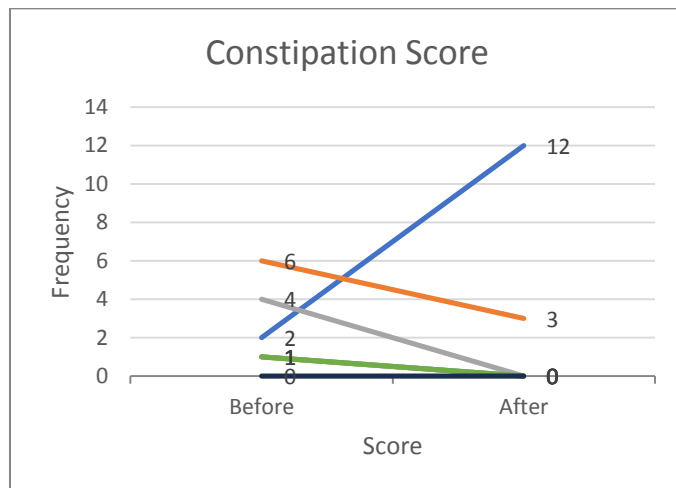


Figure 5 Constipation scores core in GSRS before and after treatment

After the completion of standard triple therapy for 14 day, the total GSRS and the abdominal pain score, indigestion score and reflux score decreased significantly. Thus an overall improvement in symptoms is seen after the successful eradication of *H.pylori* using standard triple therapy for 14 days.

Discussion

Helicobacter pylori infection is the most common gastro-intestinal infection which affects about half of the world’s population. The prevalence of *H. pylori* infection ranges from 30% in developed countries to 80-90% in developing countries indicating that socioeconomic status and living standards contribute to the same⁽¹³⁾. It is estimated that 13-90% of the global prevalence is contributed from Asian countries, mostly Bangladesh and India. The *H. pylori* infection is the major cause of peptic ulcer disease, gastroesophageal reflux disease, heartburn and dyspepsia.

H. pylori infection can be treated by triple therapy, quadruple therapy, concomitant therapy, hybrid therapy, rescue therapy or sequential therapy⁽¹⁴⁾. In our study, triple therapy regimen were followed for patients who had positive results for rapid urease tests and virology screening. The triple therapy consists of amoxicillin (1000 mg) + Clarithromycin (500 mg) + Proton pump inhibitors (40 mg) which were given twice daily for 14 days.⁽¹⁴⁾ This study aims to determine the symptomatic betterment achieved by patients following triple therapy. It was

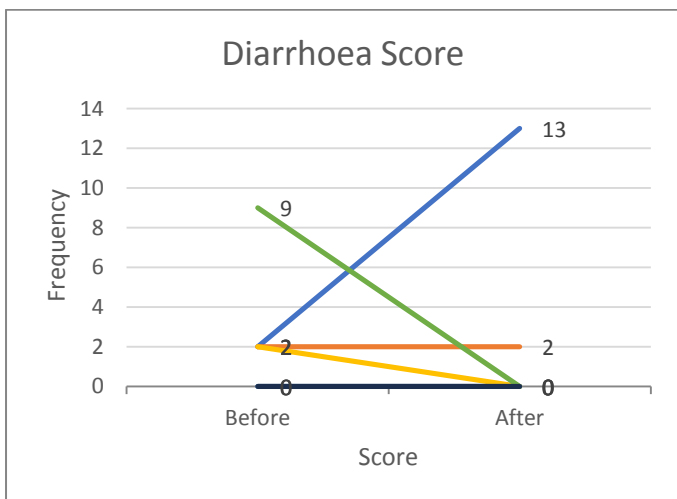


Figure 4 Diarrhea score in GSRS before and after treatment

done by obtaining the gastrointestinal symptom rating score or GSRS twice during the study, first when the patient was diagnosed to have *H. pylori* infection and second after the 14 days treatment course. In a recent study Verma and Giaffer reported based on a large scale prospective study in primary care in UK, that successful *H. pylori* eradication therapy could improve the quality of life of in patients and a significant reduction in GSRS scores is obtained after *H. pylori* eradication.⁽¹¹⁾ In the present study, symptomatic betterment were achieved by patients which were estimated through calculating the significant reduction in the GSRS scores that were collected before and after the course of therapy. Through this study we obtained 71% reduction of symptoms.

Although many other therapeutic strategies can be used for the treatment of *H. pylori*, triple therapy still persists as the first line therapy for *H. pylori* infection and no other therapies prove any significant difference⁽¹⁵⁾. If appropriate therapeutic measures are followed effective treatment outcomes can be obtained.

Every patients were observed with a reduction of symptoms and an overall decrease of symptoms were also observed. Several scores were reduced such as reflux score, abdominal pain score, indigestion score, diarrhea score and constipation score. Hence this study proves that treating *H. pylori* infected patients with triple therapy can produce betterment in patients by reducing their symptoms.

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