RESEARCH ARTICLE

A Prospective Observational Study on the Impact of Triple Therapy Alone or in Combination with Probiotics to Improve the Quality of Life in *H. pylori* Infected Patients

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Abstract

Objective: The main objective of the current study was to assess the impact of triple therapy alone or in combination with probiotics to improve the quality of life in *H. pylori*-infected patients.

Methods: In this prospective observational study, 120 subjects participated. Quality of life instrument for chronic diseases-peptic ulcer (QLICD-PU) scale, which consists of a set of questions, was used to assess the patient's symptom severity. Based on the QLICD-PU scale, the subjects were divided into categories, i.e., mild, moderate, severe and prescribed with *H. pylori*- kit in combination with probiotics and reviewed the patient efficacy.

Results: From the analysis of severity score assessed using the QLICD-PU scale, on the first day of the visit, patients with severity were found to be 87% (n = 104), moderate was 13% (n = 16), and mild were 0, and after two follow-ups over a period of 6 months the patients with symptom severity were 0, moderate was 2.5% (n = 95), mild was 77.5% (n = 22) and completely cured subjects were 20% (n = 24).

Conclusion: From our study, we concluded that *H. pylori* kit shows more effect when prescribed in combination with probiotics than when prescribed alone, as most of the patients prescribed with a combination of *H. pylori* kit with probiotics attain more effects than the patients prescribed with *H. pylori* kit alone.

Keywords: *Helicobacter pylori* infection, QLICD-PU, *H. pylori* kit, Probiotics, Combination therapy.

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INTRODUCTION

Helicobacter pylori is a gram-negative, flagellated bacterium that is often found on the luminal surface of the gastric epithelium. It is well known as the main cause of gastritis, gastroduodenal ulcers, MALT (Mucosa Associated Lymphoid Tissue) lymphomas, and gastric cancer. For treating *H. pylori*, standard triple therapy, a combination treatment that involves an *H. pylori* kit (Proton pump inhibitor (PPI), Amoxicillin, and Clarithromycin), is the most commonly recommended first-line therapy for 14 days. In recent years, the efficacy of standard triple therapy for *Helicobacter pylori* eradication has decreased. To overcome this factor, some clinicians have added probiotics like *Lactobacillus* and *Bifidobacterium* to the standard triple therapy. However, it is unclear whether standard triple therapy given in combination with probiotics may improve the efficacy and subject quality of life. In the present study, we aimed to compare the triple therapy (*H. pylori* -kit) given alone or in combination with probiotics to improve the patient's quality of life. [1-3]

Materials and Methods

Study Design

A hospital-based prospective observational study.

Study Site

This study was conducted at the gastro and liver hospital, Narasaraopeta. The patients who visit this hospital are usually from in and around the districts of Palnadu, Guntur, and Prakasam.

Study Period

The study was conducted over 6 months.

Sample Size

A total of 120 subjects with *H. pylori* were included in the study. Those who fulfilled the exclusive and inclusive criteria were selected for the study. [1]

Study Criteria

The study will be carried out by considering the following criteria:

Inclusive Criteria

- Both male and female patients with *H. pylori* positive were considered.
- People aged 13 to 75 years were included in the study.
- People with comorbidities like HTN, Diabetes mellitus, CKD, etc., were also considered =
- People who had undergone by surgery but not gastric.
- People who are newly diagnosed and past diagnosed with *H. pylori.*
- People who are ambitious to alcohol and smoking were considered

Exclusive Criteria

- People with ages <13 and >75 years were excluded from the study.
- People with NSAID'S induced PUD and *H. pylori*-negative are excluded.
- People who had undergone recent gastric surgeries.
- People who have been using antibiotics for the past 2weeks were excluded.
- Pregnant and breastfeeding women were excluded.
- People who were not willing were excluded. [4-7]

Results and Discussion

Age-wise Distribution

Age- wise distribution of *H. pylori infection* among selected subjects are shown in Figure 1. Individuals of the age group 33 to 42 years had the highest incidence of *H. pylori* (n = 34). Followed by age group 23 to 32 years (n = 31) and 43 to 52 years (n = 26), 53 to 62 years (n = 14) and 13 to 22 years (n = 12). In contrast, the age group 63 to 72 years had the lowest incidence of *H. pylori* (n = 3).

Gender Wise Distribution

Gender wise distribution of *H. pylori* among selected subjects is shown in Figure 2. Among 120 subjects, 40 were female and 80 were male.

Aetiology Wise Distribution

Eitology wise distribution in *H. pylori* infection among patients with various etiologies is shown in Figure 3. Among the total subjects, idiopathic patients are mostly infected (n = 77) followed by alcoholic (n = 25) and smoking (n = 18).

Social History-wise Distribution

The distribution of subjects based on social history is shown in Figure 4. Most of the subjects don't have any social history (n = 80), followed by alcoholics were (n = 22) and smokers are the least proportion (n = 18).

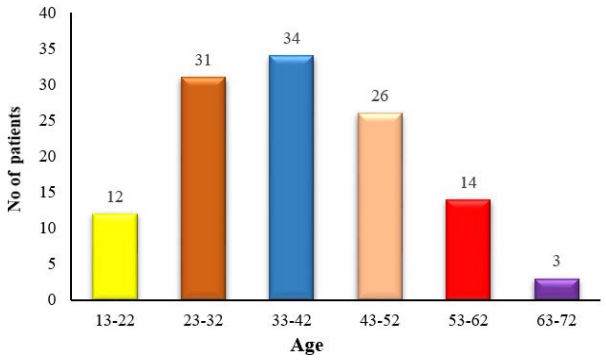

Figure 1: Age wise distribution of *H. pylori* infection among selected subjects

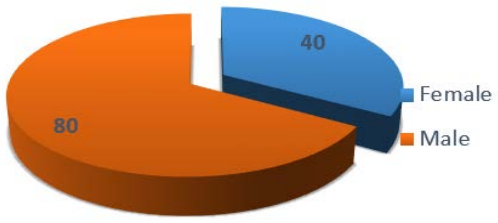

Figure 2: Gender wise distribution of *H. pylori* among selected subjects

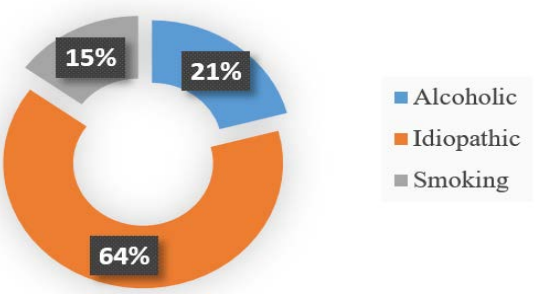

Figure 3: Aetiology wise distribution in *H. pylori* infection among patients

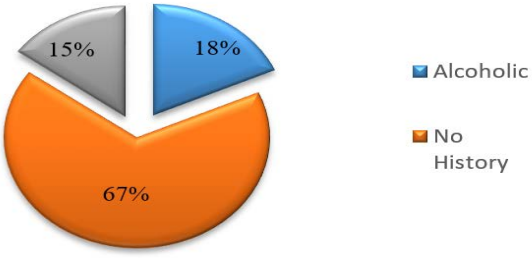

Figure 4: Distribution of selected subjects based on social history

Comorbidities Wise Distribution

Distribution of subjects based on comorbidities as shown in Figure 5. Among all the selected subjects most of the population has no comorbidities (n = 101), followed by subjects with HTN (n = 12) and subjects with DM (n = 6).

Distribution Based on Type of Gastritis in *H. pylori* infection

The distribution of subjects based on the type of gastritis in *H. pylori* is shown in Figure 6. The most common type of gastritis in *H. pylori* among the selected population is antral gastritis (n = 51) followed by erosive gastritis with *H. pylori* (n = 30) than alone (n = 5). Osteoarthritis of the ankle and shoulder is are least commonly reported.

Severity on Admission

Distribution of subjects based on first day visit to hospital. Among the collected data most subjects suffer with severe pain 87% (n = 104) followed by moderate pain 13% (n = 16). The same was presented in Figure 7.

Severity comparison between on admission and follow-up I

Distribution of subjects about the severity comparison between on admission and first follow-up,among the patients mostly suffer from severe pain were 87% (n = 104) on first-day visit and 0% (n = 0) on follow-up 1, followed by moderate pain were 13% (n = 16) on first-day visit and 79% (n = 95) on follow-up 1, patient suffer from mild pain were 0 (n = 0) on 18% (n = 22). On first follow-up,and completely cured were 0% (n = 0) on the first day visit and 3% (n = 3) on first follow-up. The same was presented in Figure 8.

Severity on follow-up I and follow-up II

Distribution of subjects based on subjects severity on follow-up 1,2: among them, mild was 77.5 (n = 22) on follow-up 1, they became higher in follow-up 2 (n = 95), moderate was 2.5% (n = 95) on follow-up 1, they become least in follow-up 2, Followed by severe 0%(n = 0) on follow-up 1and follow-up 2, 20% are completely cured (n = 3) on first follow-up, they become higher in follow-up 2 (n = 24). The same is presented in Figure 9.

Distribution based on follow-ups

Distribution of subjects based on their severity on day visit, follow-up one and follow-up two among the patients (n = 104), becomes (n = 0) on follow-ups 1 and 2. Moderate were (n = 16)it becomes higher in follow-up 1 (n = 95) on second follow-up its becomes(n = 3). Mild on admission it becomes higher in follow-up 2 (n = 93) on follow-up 1(n = 22). Completely cured subjects are more in follow-up 2 (n = 24) than in follow-up (n = 3). The same was presented in Figure 10.

Class of drugs prescribed

Distribution of subjects based on a class of drugs shown in Figure 11, *H. pylori* kit + probiotic +syrup 75% (n = 90) were mostly prescribed drugs and followed by 18% (n = 21) *H. pylori* kit alone, 3 %(n = 4) *H. pylori* kit +syrup, and *H. pylori* + probiotic, 1 %(n = 1) lowest proportion.

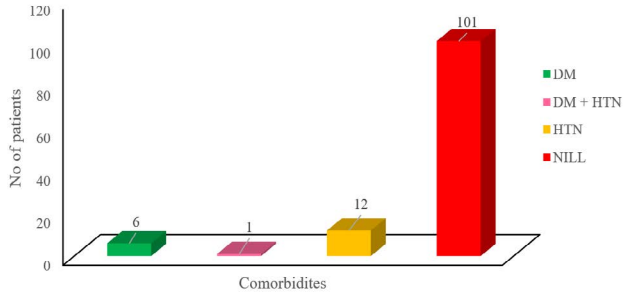

Figure 5: Distribution of selected subjects based on comorbidities

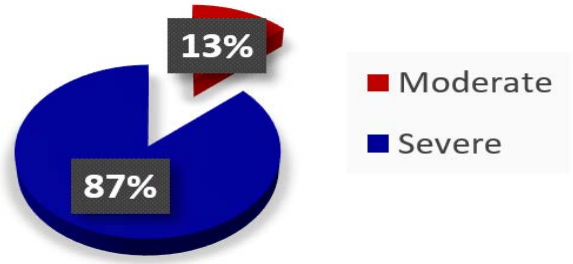

Figure 7: Distribution of selected subjects based on Symptom severity of First day Visit

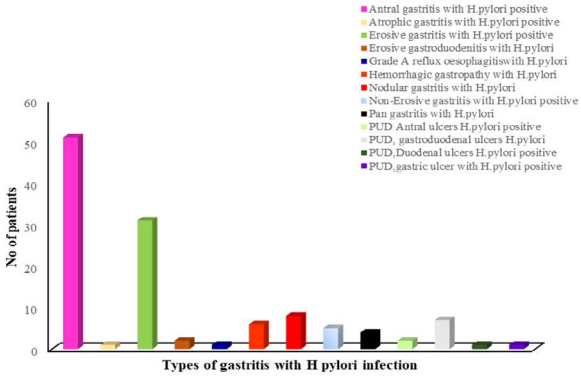

Figure 6: Distribution of selected subjects based on types of gastritis in *H. pylori*

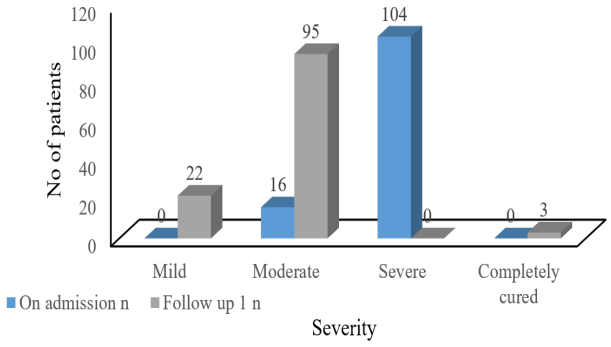

Figure 8: Distribution based on severity comparison between on admission and first follow-up

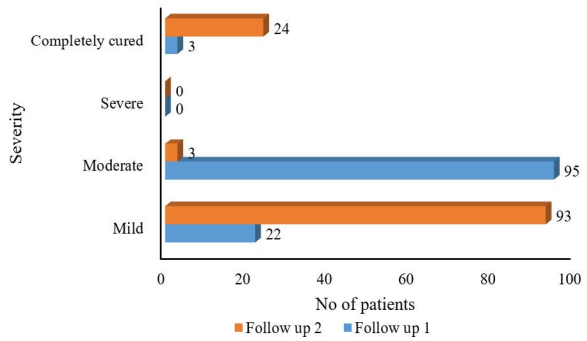

Figure 9: Distribution based on comparison of severity on follow-up 1 and 2

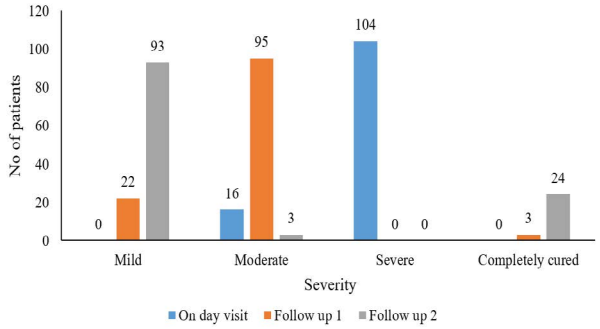

Figure 10: Distribution based on severity on day visit, follow-up 1 and follow-up 2

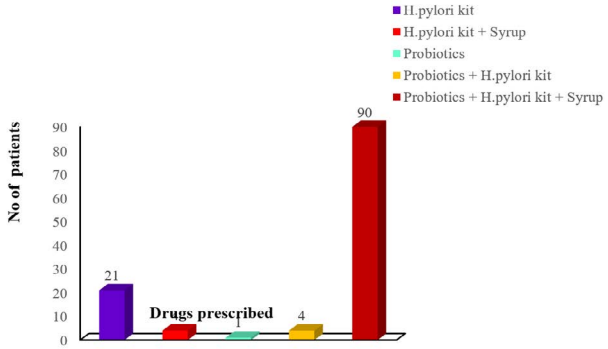

Figure 11: Distribution of selected subjects based on Class of drug

Distribution based on type of drugs prescribed

The distribution of subjects based on treatment patterns is shown in Figure 12. The mostly prescribed treatment is esomac kit + probiotic+ syrup and probiotics are prescribed in different brands like 18 % (n = 21) esomac *H. pylori* kit + bifilac + maharaft , 13% (n = 15) esomac hp kit+ bifilac, instaraft ,followed by 9% (n = 11) esomac hp kit + happibiotic +aroraft,8% (n = 9) esomac hp kit + maharaft + sibogut,3% (n = 4) esomac hp kit + maharaft and esomac+instaraft+sibogut3%(n = 3) Esomac hp kit + bifilac +aroraft , 2% (n = 2), esomac + gutfix +aroraft and esomac + gutgermina + instaraft and esomac + bifilac + aroraft, esomac+ Happibiotic + maharaft and gutfix +instaraft, 22%

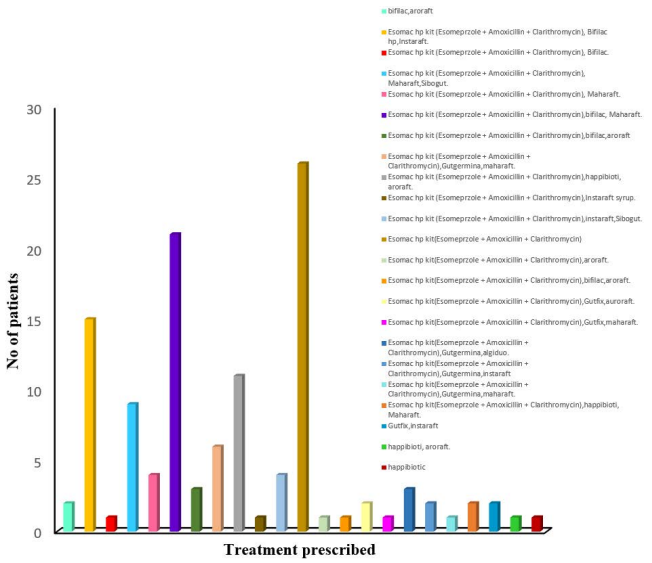

Figure 12: Distribution of selected subjects based on treatment pattern

(n = 26) esomac hp kit alone 1% (n = 1) , esomac+ bifilac and esomac + instaraft, esomac+ aroraft, esomac + gutfix + maharaft ,happibiotic + aroraft, happibiotic. The highest proportion of subjects were used esomac + probiotic + syrup and least proportion were used alone probiotic or alone syrup combination.f[8-10]

Discussion

In this study, we performed a prospective observational study on impact of triple therapy alone or in combination with probiotics to improve the quality of life in *H. pylori* infected patients.

We have collected the required information like demographic details, past medical history, surgical history and etiology, comorbidities, and social history by interacting with patients. All the details during we recorded the symptoms and severity of patients on the first visit by using QLICD-PU SCALE throughout the study. We conducted two follow-ups to the subjects and recorded their symptoms severity.

We concluded our study based on symptom severity results from the 1st day of visit to the two follow-ups. We have calculated our sample size as 120 based on the N-masters formula as *H. pylori* is a gram-negative bacterial infection that causes some gastric diseases like antral, erosive and non-erosive, PUD, and hemorrhagic ulcers, pan gastritis, nodular gastritis, etc. It will develop to any age group of people. Because, it becomes a common problem now a days. Hence, higher incidence rates are found idiopathically than smokers and alcohol.

In our study, out of 120 subjects, the highest proportion of *H. pylori* infection 28% (n = 34) was observed between the age group of 33 to 42 years, followed by people who are aged between 23 to 32, which occupy 26% (n = 31) of the total

sample size. People who are aged between 43 to 52 years occupy 22% (n = 26) and, followed by people who are aged between 53-62 years occupy 12% (n = 14) and followed by people who are aged between 13-22 years occupy 10% (n = 12) and the total sample size of age between 63-72 occupies the least proportion of 3% (n = 3) of total sample size.

From our data, the proportion of *H. pylori* infection in males was found to be 67% (n = 80) and the proportion of *H. pylori* infection in females was found to be 33% (n = 40). Hence, the largest proportion of patients were found in males than females, which was following many research studies that stated men's are more prone to *H. pylori* infection because of their social habits like smoking and alcohol. As per our data, most of the subjects are idiopathic etiology 64% (n = 77), alcoholics 21% (n = 22) and smokers 15% (n = 18%).

Out of 120 subjects, on social habits, 67% (n = 80) had no social history followed by alcoholics were 18 %(n = 22), smokers were 10% (n = 18).

As per our data most of the *H. pylori*-infected patients are the absence of comorbidities 84% (n = 101) followed by HTN patients 10% (n = 12), diabetic patients are 5% (n = 6) and both HTN + DM patients are least proportion 0.8% (n = 1) of total sample size.

In our study out of 120 subjects, 43% (n = 51) of the patients were diagnosed with antral gastritis with *H. pylori*-positive and followed by 26%(n = 31) erosive gastritis, 7% (n = 8) nodular gastritis, 6% (n = 7) PUD gastro duodenal ulcers, 5%(n = 6) with hemorrhagic gastropathy, 4% (n = 5) non-erosive gastritis, 3%(n = 4) with pan gastritis, 1% (n = 2) with both PUD antral ulcers and erosive gastroduodenitis, 0.8% (n = 1)with grade A reflux esophagitis, PUD, duodenal ulcers, and the gastric ulcers were occupied least proportion. As per our study out of 120 subjects 67% (n = 80) subjects are they don't have any social history. Followed by 18% (n = 22) are alcoholics, 15% (n = 18) of subjects are habitual to smoking which is least proportion than alcoholics.

As per our data on admission most of the subjects suffered with severe symptoms 87% (n = 104), moderate symptom 13% (n = 16) and mild were 0.

During follow-up 1, out of 120 subjects 22 subjects were in mild condition, 95 subjects were moderate, no severe and three patients were completely cured after continuing medication or modifying the regimen patients were again asked to approach for a second follow-up after 2 weeks.

During follow-up 2, out of 120 subjects 93 subjects were in mild condition, 3 subjects were in moderate, no severe and 24 subjects were completely cured. By comparing the results recorded from the follow-up 1 and 2 that *H. pylori* kit in combination with probiotics shows more effect.

In our study different treatment patterns were prescribed among them 75% (n = 90) *H. pylori* kit + probiotics + syrup were mostly prescribed, followed by 18% (n = 21) *H. pylori* kit alone, 3% (n = 4) *H. pylori* kit + syrup, *H. pylori* kit + probiotics and 1% (n = 1) probiotics alone.

In our study we observed many brands of probiotics and with a combination of esomac hp kit 18% (n = 21) esomac hp kit + bifilac + maharaft, 13% (n = 15) esomac hp kit + bifilac+ instaraft followed by 9% (n = 11) esomac hp kit + happibiotic+ aroraft, 8% (n = 9), 22% (n = 26) subjects were used esomac hp kit alone. Esomac HTN + DM patients are least proportion 0.8% (n = 1) of total sample size.

Conclusion

From our study, we conclude that *H. pylori* kit (Esomeprazole+ Amoxicillin+ Clarithromycin) shows more effect when prescribed in combination with probiotics than when prescribed alone. As most of the patients prescribed with a combination of *H. pylori* kit with probiotics attain more effects than the patients prescribed with *H. pylori* kit alone.

In our study the sample size was estimated as 120 based on N-masters formulae. As per inclusive and exclusive criteria, we have collected 120 cases. All the subjects were prescribed with *H. pylori* kit in combination with probiotics along with other adjuvant medications and the subjects twice. We used the QLICD-PU scale, which consists of questionnaires regarding the symptoms of *H. pylori*. Patients were asked about a set of questionnaires to give a score during the first day of the visit and the other two reviews and observed for symptoms disappearance.

From our data, on by the examination of RUT dry test, the proportion of *H. pylori* infection was more prone in males than in females because of their social habits like smoking and alcohol than in females, most of the patients diagnosed with antral gastritis with *H. pylori* positive.

Out of 120 patients, 11 patients complained about the reoccurrence of the symptoms. The symptoms are chest tightness, belching, stomach pain, and bloating because they didn't follow the proper diet and medications.

In this study after examining the results recorded after all the reviews, we found that the combination of *H. pylori* kit with probiotics shows greater effectiveness than the *H. pylori* kit alone.

In past studies, long-term use of probiotics reports shows the disguised (alteration in taste) in most of the patients to that problem. We counseled the patient about the dietary alterations and lifestyle modifications and we provided awareness to patients regarding *H. pylori* infection, which may lead to gastric cancers if left untreated.

We conclude that standard triple therapy is encouragingly efficacious as a first-line treatment for *H. pylori* infection only in combination with probiotics.

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APPENDIX

QLICD- PU SCALE

1. Did you have pain/heart burn (sore/blunt painful/burning pain/swelling) in epigastria?
2. Did you have pain or discomfort in abdomen at night or at hungry?
3. Would your upper abdomen pain/uncomfortable feeling be relived after dinner?
4. Did you have acid regurgitation?
5. Did you have any belching/ bloating?
6. Did you feel fullness in the upper abdomen/abdominal distension?
7. Did your bowel movements normal or troubled by constipation/diarrhea?
8. Did you had a good appetite?
9. Have you been troubled by nausea and vomiting?
10. Do you drink alcohol/Do you smoke cigarette?

Note: 1-4 (Mild), 5-7 (Moderate), 8-10 (Severe)

Questionnaire Form Used in the current study