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RESEARCH ARTICLE

EFFICACY AND TOLERANCE OF TRIPLE THERAPY IN ERADICATION OF HELICOBACTER PYLORI

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Abstract

Aim: To evaluate the efficacy and tolerance of triple therapy in eradication of Helicobacter pylori.

Subjects and methods: Our study is a prospective observational study conducted at the gastroenterology dept in tertiary care hospital, Hyderabad, and accepted by the institutional ethical committee. A total of hundred subjects who were positive for infection of helicobacter pylori was screened by the procedure of endoscopy RUT mentioned in the study based on inclusion & exclusion criteria. Subjects were treated with triple therapy for fourteen days. After completion of fourteen-days therapy, assessment of Helicobacter pylori eradication was carried out after four weeks by the stool antigen test.

Results: In the total of hundred subjects, 60 male and 40 female subjects and 44.66 yrs is the mean value of age. total hundred subjects, successful eradication rate was seen in 91 subjects and eradication failure was seen in 9 subjects against helicobacter pylori infection.

Conclusion: Standard triple therapy is considered as first-line therapy for the infection of Helicobacter pylori eradication for the past two decades and the effectiveness of triple therapy is variable regionally. so, we are concluding that a 91% success rate was seen in our region with triple therapy and it is well tolerated because no subjects were discontinued therapy due to adverse effects.

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Introduction:-

H. pylori are one of the maximum well-known pathogens and it's been anticipated that it constitutes half of the planet's population [1]. It's formerly called Campylobacter pylori [2]. It's a gram-negative, spiral-shaped, micro-aerophilic, flagellated bacteria (see fig.1). It had been first recognized by warren and marshall. These microorganisms have morphological traits that penetrate the mucosal membrane and colonize the duodenum and stomach [3].

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Helicobacter pylori are accountable for the pathogenesis that results in gastric adenocarcinoma, peptic ulcer, gastric MALT lymphoma and gastritis. The WHO has labeled *Helicobacter pylori* as a set one carcinogen with the threat of stomach cancer. *Helicobacter pylori* associated stomach cancer accounts for 5.5% of all cancers globally and 25% of malignancies related to infection. *Helicobacter pylori* are associated with extraintestinal diseases including Alzheimer's, iron deficiency anemia, coronary artery disease [3]. *Helicobacter pylori* are liable for ninety percent of small intestinal ulcers and 80 to 85% of stomach ulcers. Reinfection rates by *H. pylori* are around 20 to 30 % per year in developing countries which is high and is low in developed countries around 0.3-1.0% per year. Certain factors responsible for causing *Helicobacter pylori* such as Ulcerative strains of *h pylori*, hosts expose to ulcers, age, and interaction with other ulcerogenic factors such as NSAIDs that determine the development of peptic ulcers disease. For the patients who are using NSAIDs, the chance of ulcers due to *h pylori* infection isn't clear but shows an additive effect. Long-term NSAID users are at risk for stomach ulcers who tested positive for *helicobacter pylori*. Eradication of *H. pylori* in those subjects previous to have NSAIDS remedy has proven to lessen the chance of peptic ulcer associated with *H pylori* NSAIDs [4].

Nearly 66.7% of the world's population are infected with *Helicobacterpylori* infection and which is most common in growing countries [5] and the most common infection in the world [6]. The infection rate varies from country to country; in developing countries, the infection rate is much higher than in western countries, and it is anticipated to be about 25%.

The infection rate in kids in growing nations is higher than in developed countries, which may be due to poor sanitation and may be related to the fewer antibiotics utilization for other disease conditions, [7]. *Helicobacter pylori* infections are mainly transmitted by the oral and oral-fecal routes. The risk factors for *H. pylori* infection are low socio-economic class, bed-sharing and, exposure to overcrowding.

Aim &Objectives:-

Aim:-

To evaluate the efficacy and tolerance of triple therapy in the eradication of *Helicobacter pylori*.

Objectives:-

To evaluate the efficacy and tolerance of standard triple therapy in eradicating *Helicobacter pylori* infection.

Determine the incidence of *Helicobacter pylori* infection.

Materials And Methods:-

Study site:

The present study was conducted in the Gastroenterology department, KIMS hospital Hyderabad.

Study design:

the study design is Prospective Observational Study."

Study period:

Six months.

Sample size:

100 subjects.

Study criteria:

Inclusion criteria:

Subjects with the condition of suspected or diagnosed with dyspepsia and *H. pylori* infection.

Subjects with age between 18 to75.

Exclusion criteria:

Pregnant and lactating women

Subjects with a history of *Helicobacterpylori* infection.

Cancer subjects.
Subjects Allergic towards antibiotics.
Subjects below 18 years and above 75 years.

Methodology:-

Our study was a prospective observational study conducted at the gastroenterology dept in tertiary care hospital, Hyderabad. The present study was accepted by the institutional ethical committee and carried out in accordance with ethical standards.

A total of hundred patients, who were positive for infection of helicobacter pylori screened by the procedure of Endoscopy & RUT mentioned in the study based on inclusion and exclusion criteria

Exclusion criteria included subjects with a history of infection of *Helicobacter pylori* & recent use of antibiotics and PPI and subjects with gastric cancers or other malignancy and prior allergic reactions towards the drugs included in the study as well as pregnancy and breastfeeding females.

Inclusion criteria include patients with age between 18-75 years

Informed consent was obtained from the participants at the beginning of the study.

The details of the patients and the findings were recorded. And subjects treated with triple therapy for fourteen days. Assessment of eradication of *h.pylori* was carried out after the completion of 14 days of therapy a time gap of 4 consecutive weeks is taken, then a stool antigen test is done for assessment of eradication of *H.pylori* infection.

After completion of 14 days of therapy, assessment of helicobacter pylori eradication was carried out after four weeks by the stool antigen test.

Results:-

A total of hundred(n=100) *Helicobacter pylori* positive subjects were screened and included in the present study according to exclusion and inclusion criteria from gastroenterology dept in KIMS hospital in which all subjects were treated with triple therapy included Esomeprazole 40mg & Amoxicillin 750mg & Clarithromycin 500mg Every drug was given two times in a day.

The study comprised of 100 subjects, 44.66 years is the mean age and grouped according to the age groups 18-30 aged were 22(22%), 31-45 aged were 26(26%), 46-60 aged were (36%) ,61-75 aged were 16(16%) as shown in

AGE GROUP	NO OF PATIENTS
18 -30	22(22%)
31-45	26(26%)
46-60	36(36%)
61-75	16(16%)

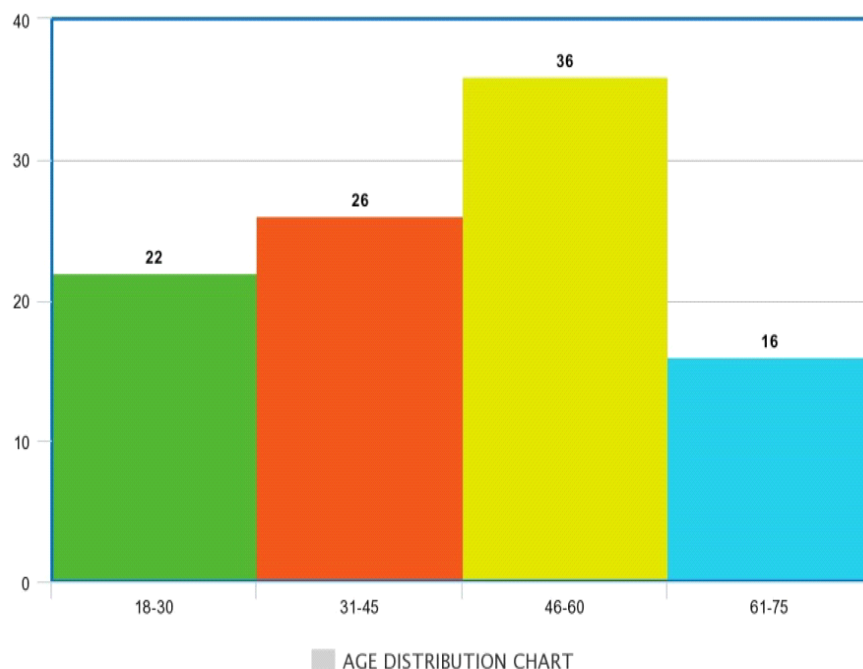


Fig 7:- Age distribution of subjects.

The subjects were grouped according to gender, where males were 60(60%) and females were 40 (40%) as shown in fig 8

Count of SEX

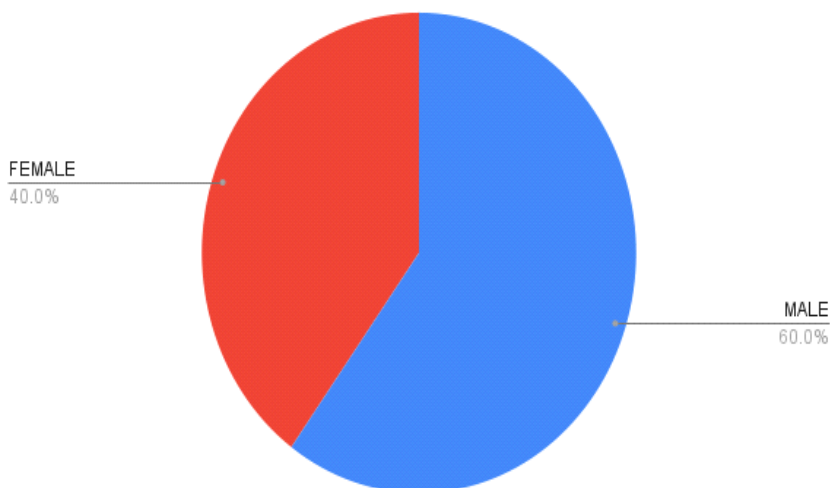


Fig 8:- Subjects according to gender.

Chief Complaints:

In total 100(n=100) subjects, the cause to do RUT is taken as the consideration, chief complaints were 6 cases of abdomen pain and bloating (6%), 4 cases of heartburn(4%), 2 cases of both abdomen pain and nausea (2%), 4 cases of diarrhea and abdomen pain (4%), 14 cases of abdomen pain and abdomen burning (14%), 2 cases of bloating abdomen pain and reflux (2%), 8 cases of both bloating and reflux (8%), 4 cases of only reflux (4%), 10 cases of both reflux and abdomen pain (10%), 40 cases of dyspepsia (40%) as seen in fig 9.

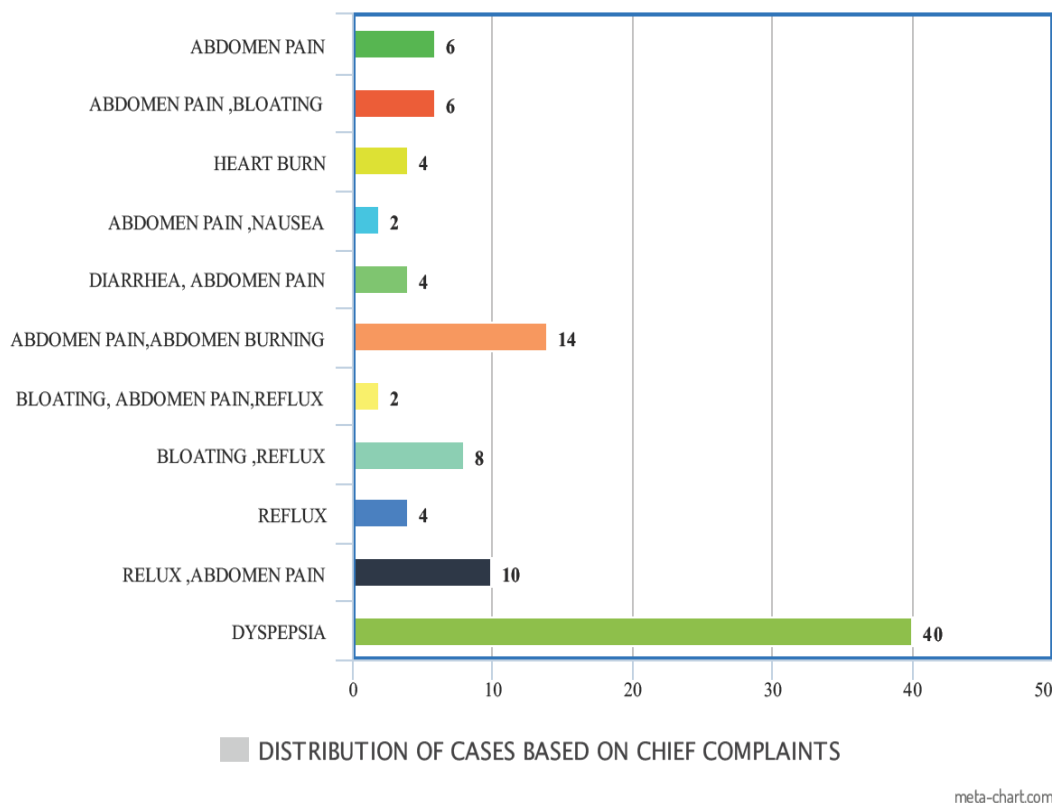


Fig 9:- Subjects distributed based on chief complaints.

Subjects distributed based on diagnosis:

In a total of 100(n=100) subjects non-erosive gastritis is seen in 46(46%) cases, both non-erosive gastritis and small hiatus hernia is seen in 20(20%) cases, erosive gastritis is seen in 26(26%) cases, erosive gastritis and small hiatus hernia is seen in 4(4%) cases, erosive duodenitis seen in 2(2%) cases, duodenal ulcer and non-erosive gastritis is seen in 2(2%) cases as shown in Fig 10

Fig 10:- Distribution of subjects based on diagnosis.

Stool Antigen Test Report:

The table presents the analysis of stool antigen tests for the subjects (n=100) who are included in the present study, stool antigen test was done for 100(100%) subjects out of which 91 subjects (n=100, 91%) showed stool antigen test negative and 11 subjects (n=100, 11%) showed positive for H pylori, information is represented in Fig 11

Stool antigen test	No of reports	percentage
No of subjects shown + -ve for H.pylori	9	9%
No of subjects shown negative for H.pylori	91	91%

Fig 11:- Presents the analysis of stool antigen test.

Clinical Outcome:

All the collected data were analyzed and the tolerance & efficacy of standard triple therapy in the eradication of H. pylori was evaluated.

The clinical outcome when triple therapy is given to 100 subjects who are diagnosed with *Helicobacter pylori* positive was found out, where 91 subjects accounting for 91%(n=100) had eradicated and the number of non-eradicated stands at 9 resulting in 9%(n=100) as shown in Fig 12

Fig 12:- Clinical outcome of the study

Discussion:-

All authorities suggested that standard triple therapy was the primary choice for the eradication of *Helicobacter pylori* infection for the past two decades. Several factors influenced the *H.pylori* eradication rate those were antibiotic resistance, incompatibility to therapy, drug-related adverse effects, bacterial load, comorbid conditions, the habit of smoking, and some gene differences in metabolism of PPI [8].

The aim of this present study was to evaluation of the effectiveness and tolerance of standard triple therapy in *Helicobacter pylori* eradication. In our study total of 100 patients were participated from the age of 18 to 75 years in those 60 male patients and 40 female patients and 44.6 years mean value of age. Most of the subjects complained of dyspepsia 40% and both abdominal pain&burning 14%, heat burn 4% of the subjects, bloating&reflux was seen in 8% of cases. In upper gastrointestinal endoscopy, we found gastritis without erosions 46% and hiatus hernia with gastritis without erosions were seen in 20% and gastritis with erosions in 26% and in a small percentage of subjects seen duodenal ulcers and duodenitis with erosion was 2%. And overall triple therapy eradication rate was found to be 91% in our study.

Gebeyehuendalew et al, reported that the eradication rate of *Helicobacter pylori* infection by triple therapy was found to be 90.3% in northwest Ethiopia. In this study reported eradication rates were close to our study eradication rates [9].

Kubra Hussani SZ et al conducted prospective observational bottom-up study with 60 subjects in Hyderabad, India .in this study triple therapy eradication rate was achieved to be 100% after the duration of 30 days of treatment, and compared to our study sample size was small and triple therapy duration was 30 days.[10].

Dr pravin m rathi et al examined the effectiveness of *Helicobacter pylori* density on the efficacy of STT In Mumbai with 120 subjects, males and females were 58%&42% respectively, and the mean age was 31 yrs. In their study, 45% complained of heartburn but in our study, 4% of subjects experienced and more subjects complained of dyspepsia in their study similar to our study, and 80% successful eradication rate was noticed in their study close to our study[11].

One study conducted in Sikkim, Mona Dhakal et al conducted a hospital-based observational study in 100 subjects in that males and females were 63%&37% respectively, and the mean age was 38 years. In upper gastrointestinal findings, they were seen as gastritis more and reflux condition was less than 1% similar to our study and 30% duodenal ulcers was found but we have seen in 2 percent of subjects only. In their study, they reported that the *H.pylori* eradication rate of STT was found to be 63% But in our study eradication rate was 91%.[12].

Dr graham et al, through their study, informed that *H pylori* prevalence was found to be 60% means approximately 700 to 800 million population infected with *H pylori*. and this study reported that triple therapy with a combination of tinidazole and clarithromycin were found to be 65% and 42% respectively in Mumbai. but in new Delhi eradication rate was completely controversial by same regimens 80% success in 14 days and 91% success in 21 days similar to our study eradication rates of triple therapy and they concluded that clarithromycin containing triple therapy was more effective in places where clarithromycin resistance was 7 to 10%[13].based on articles reported in Malaysia one study confirmed that the eradication rate of triple therapy was found to be 90%. And it was described that a recent national survey reported in the Malaysia eradication rate from 2001 to 2007 was 84.9 to 87.5 % and 2008 to 2010 were 80 to 81% respectively. This article showed that eradication rates of standard triple therapy several countries from several articles those were 92% in Hong Kong, Canada and Europe greater than 80%, Iranian lower than 60%, and Italian countries 70 to 80% so this study described that eradication rates of triple therapy varying in different regions and different countries and populations[14].

Gokul D et al, included in their study population 18 to 68 years and mean age was 41.2% it was close to our mean age value. and female positive patients more in their study compared to males but in our study male positive patients

were predominant. And they investigated that triple therapy eradication rates with metronidazole and amoxicillin results in 93% and 90% similar to our study and they finally concluded that there is no significant variation was noticed in those regimens[15].

William duck et al, reported that in the developing countries incidence of helicobacterpylori infection was 4 to 15 percent yearly, but the incidence was found to be 6.67 percent in our study [16].

So based on these studies we were concluding that eradication rates of a triple therapy of some studies were closer to our study and some other eradication rates were contrary to our study so depending on all observations eradication rates of triple therapy varying in different populations in different regions. So finally we are suggesting these results does not apply to other populations or other regions or other countries.

Conclusion:-

Standard triple therapy is considered as first-line therapy for the infection *Helicobacter pylori* eradication for the past two decades. Our study demonstrated that in total of 100 patients, the *Helicobacterpylori* infection was eradicated in 91 patients after received the Triple therapy regimen. So 91% successful eradication rate was seen in our region with triple therapy. in some regions and countries and population eradication rate of triple therapy showed less effectiveness and in some regions showed better efficacy vice-versa. So we are concluding that triple therapy is showing good tolerability because no subjects were discontinued therapy due to adverse effects and a 6.67% incidence of helicobacterpylori infection was seen in our study. More long-term prospective studies with a large sample size are required from India to know the accurate efficacy. Patient compliance place a crucial factor for the success of any therapy and improved sanitation and hygiene is better for good health. Limitations of the study are these results do not apply to other countries and regions

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