



## COMPARISON OF ERADICATION RATES OF H.PYLORI BETWEEN STANDARD TRIPLE & DUAL DRUG REGIMEN THERAPY

### Gastroenterology

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### ABSTRACT

**BACKGROUND & AIMS:** Helicobacter pylori is the most common chronic bacterial infection in the world with prevalence varying worldwide. To compare the eradication rates of H.pylori between treatment with 2weeks Clarithromycin based triple drug regimen & 6weeks dual drug regimen containing Amoxicillin & Omeprazole in patients with gastric or duodenal ulcer disease.

**PATIENTS & METHODS:** Prospective randomized controlled study. Total sample size 197. One arm receives triple drug regimen for 2 weeks. Second arm receives dual drug regimen for 6weeks.

**RESULTS:** Total 197 patients were included in the study of which 98 patients received triple drug regimen & 99 patients received dual drug regimen. H.pylori eradication rate between the triple drug regimen & dual drug regimen is statistically significant with p value 0.0142.

**CONCLUSION:** H.pylori eradication rate with dual drug regimen for 6 weeks is inferior to Clarithromycin based triple drug regimen for two weeks.

### KEYWORDS

H.Pylori, Gastric&Duodenalulcer, Rapid Urease test

### INTRODUCTION:

Helicobacter pylori infection is the most common chronic bacterial infection in the world. The prevalence of the infection varies worldwide being as low as 10% in developed nations to higher than 80% in developing countries. The manifestations of the infection includes Gastritis, Gastric atrophy, duodenal ulcer disease, Gastric ulcer disease, primary gastric B-cell lymphoma, Gastric adenocarcinoma, Iron deficiency anemia & Vitamin B12 deficiency.<sup>1-4</sup> The most commonly recognized manifestation of H.pylori infection in india is peptic ulcer disease, particularly duodenal ulcer disease, which outcomes gastric ulcers between 8:1&30:1<sup>5</sup>.

### AIMS:

- To compare the eradication rates of H.pylori between treatment with 2weeks Clarithromycin based triple drug regimen & 6weeks dual drug regimen containing Amoxicillin & Omeprazole in patients with gastric or duodenal ulcer disease.
- To document ulcer healing rate at 4weeks after end of treatment.

### MATERIALS AND METHODS:

**INCLUSION CRITERIA:** Patients with gastric or duodenal ulcer disease who test positive for H.pylori infection on rapid urease test.

**EXCLUSION CRITERIA:** Previous anti H.pylori therapy  
Use of any study antibiotics within the preceding 30 days

Presence of serious medical conditions precluding participation in the study

Use of concomitant medications known to interact with study medication

Pregnancy  
H/o drug allergy  
Malignant appearing ulcers  
Previous gastric surgery

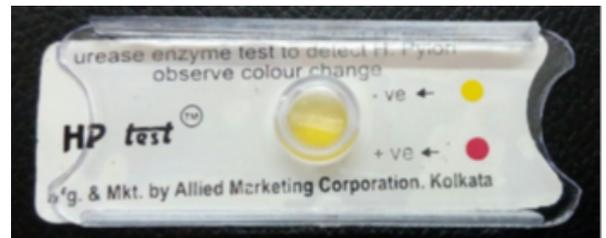
**STUDY DESIGN:** Prospective randomized controlled study. Total sample size 197 with 2 treatment arms. One arm receives triple drug regimen (clarithromycin, Amoxicillin, Omeprazole) for 2 weeks. Second arm receives Amoxicillin & Omeprazole dual drug regimen for 6weeks.

All the patients undergoing Gastroduodenoscopy and found to have either gastric ulcer or duodenal ulcer were subjected to mucosal pinch

biopsy with 7mm cusp jaw forceps, one from antrum & one from corpus avoiding areas of ulceration. Biopsy pieces were immediately placed on the gel tunnel of rapid urease test kit.

The Rapid urease test kit were observed at 30min, 1 hr & every 6hrs for upto 24 hrs, for gel tunnel colour change from yellow to pink. When turned to pink it was labelled as positive for H.pylori organism.

**Fig.1: Negative rapid urease test**



**Fig 2: Positive rapid urease test**



**STATISTICAL ANALYSIS:** Student "t" test has been used to find the significance of study parameters on continuous scale between two groups.

Chi square has been used to find the significance of study parameters on categorical scale between two groups. A p value <0.05 as taken as statistical significant.

**RESULTS:** Total 197 patients were included in the study of which 98 patients received triple drug regimen & 99 patients received dual drug regimen. In the triple drug regimen group one patient was non compliant with the medication & 10 patients were lost to follow up.

Total 173 patients (87 in triple drug regimen group ,86 in dual drug regimen group )completed the study &results were expressed as per protocol analysis unless specified otherwise.

Males are 115, Females are 58, Mean age of Males 41.30±6.88,Females mean age is 40.48±6.85. Among 173, 65 have gastric ulcers & 108 have duodenal ulcers.

Among 65 gastric ulcers 37 are located at incisuraangularis, 20 are located at corpus, 8 are located at antrum.

Out of 87 patients who received triple drug regimen 71 patients tested negative for H.pylori at 4 weeks after completion of treatment. Hence H.pylori eradication rate is 86.60%.Out of 86 patients who received dual drug regimen 56 patients tested negative for H.pylori at 4 weeks after completion of treatment .Hence H.pylori eradication rate is 65.11% . H.pylori eradication rate between the triple drug regimen & dual drug regimen is statistically significant with p value 0.0142. Intention to treat H.pylori eradication rate with triple drug regimen &Dual drug regimen is 72.44%&57.14%respectively p=0.0198.

**Table 1: H. Pylori ulcer healing rates & drug side effects**

Variable	Triple drug regimen	Dual drug regimen	P value
H.pylori eradication rate	81.60%	65.11%	0.01
Peptic ulcer healing rate	93.10%	90.69%	0.58
Gastric ulcer healing rate	86.95%	80.95%	0.53
Duodenal ulcer healing rate	95.31%	100%	0.14
Gastric ulcer healing rate in H.pylori eradicated group	100%	100%	0.00
Gastric ulcer healing rate in H.pyloriuneradicated group	0%	66.66%	0.02
Duodenal ulcer healing rate in H.pylori eradicated group	100%	100%	0.00
Duodenal ulcer healing rate in H.pyloriuneradicated group	81.25%	100%	0.25
Loose stools	12.62%	15.11%	0.63
Abdominal discomfort	8.04%	11.62%	0.42
Nausea	8.04%	8.13%	0.98
Bitter taste	5.74%	2.32%	0.25
Over all side effects	16.09%	19.76%	0.52

**Table 2: H. Pylori eradication in smokers, alcoholic, hypertension**

Variable	Triple drug regimen	Dual drug regimen	P value
H.pylori eradication in smokers	64.70%	35%	0.07
H.pylori eradication in non smokers	85.71%	62.12%	0.001
H.pylori eradication in alcoholics	84%	63.63%	0.10
H.pylori eradication in nonalcoholics	59.67%	39.06%	0.02
H.pylori eradication in diabetics	71.42%	80%	0.72
H.pylori eradication in non diabetics	28.75%	33.33%	0.52
H.pylori eradication in hypertensives	80%	57.14%	0.30
H.pylori eradication in non hypertensives	83.11%	59.49%	0.001

**Table 3: H. Pylori eradication rates among personal habits and comorbidities**

Variable	Smokers	Non smokers	P value
H.pylori eradication rate with TDR	64.70%	85.71%	0.04
H.pylori eradication rate with DDR	35%	62.12%	0.03
	<b>Alcoholics</b>	<b>Non Alcoholics</b>	<b>P value</b>
H.pylori eradication rate with TDR	84%	59.67%	0.02
H.pylori eradication rate with DDR	63.63%	39.06%	0.04
	<b>Diabetics</b>	<b>Non Diabetics</b>	<b>P value</b>
H.pylori eradication rate with TDR	71.42%	28.75%	0.02
H.pylori eradication rate with DDR	80%	33.33%	0.03

	Hypertensives	Non Hypertensives	P value
H.pylori eradication rate with TDR	80%	83.11%	0.80
H.pylori eradication rate with DDR	57.14%	59.49%	0.90

**DISCUSSION:** The first-line worldwide choice for H.pylori eradication is clarithromycin-based triple drug therapy. Which involves using a PPI and two antibiotics, amoxicillin and Clarithromycin<sup>1</sup>. This present study was undertaken with main intention to find out whether oral dual drug therapy with amoxicillin and omeprazole given for 6 weeks is superior, equal or inferior to 2weeks of standard oral triple drug regimen of omeprazole, amoxicillin and clarithromycin given for eradication of H.pylori.

This study also made decent observations of the effect of patients co-morbid health conditions, personal habits on the efficacy of both standard triple drug regimen and dual drug regimen on H.pylori eradication. This study also had an eye on the side effect profile of both standard triple drug regimen and dual drug regimen. Other main side of this study apart from H.pylori eradication is assessment of gastric and duodenal ulcer healing rate at 4weeks after end of treatment and comparison of ulcer healing rate between triple & dual drug regimen.

.In the present study H.pylori eradication rate with triple drug regimen and dual drug regimen is 81.60% and 65.11% respectively which is statistically significant (p=0.01). It dictates that dual drug therapy is far inferior to triple drug therapy with respect to H.pylori eradication.

The dual drug regimen H.pylori eradication rate observed in the present study is closer to that observed as 62.5% by Taraq A. Attumietal. H R Koelz,<sup>7</sup> in their study observed 52% eradication after treatment with amoxicillin and omeprazole for 2weeks.

H.pylori eradication rate with triple drug regimen observed in the present study is very similar to that observed by Nasa M etal<sup>8</sup>

In the present study H.pylori eradication rate with triple drug regimen among smokers is lower than that among non smokers (64.70% vs 85.71%) which is statistically significant (p=0.04). It indicates that smoking affects H.pylori eradication rate adversely. Similar observations were noted by Namiot Z etal<sup>9</sup> (smokers 65.8% vsnon smokers 91.4%. p < 0.01).In the present study with dual drug therapy smokers had statistically significant lower H.pylori eradication rates than non smokers (35%; vs 62.12%. p=0.03).

In present study H.pylori eradication rate with triple drug regimen among alcoholics is higher than in non alcoholics (84% vs 59.67%) which is statistically significant (p=0.02). Similar results were observed by Namiot Z etal where patients who drank alcohol had higher eradication rate (drinkers 85.2%, non-drinkers 59.5%. p < 0.05). In the present study with dual drug regimen also H.pylori eradication rates were statistical significantly higher among alcoholics than in nonalcoholics (63.63% vs 39.04%. =0.04).

In the present study even though the percentage of patients experiencing medication side effects is more in the dual drug regimen group than the triple drug regimen group it is not statistically significant between the two groups (19.76% vs 15.09%, p=0.52).

In the present study 86.95% gastric ulcer patients in the triple drug regimen and 80.95% gastric ulcer patients in the dual drug regimen had their ulcers healed at 4 weeks after end of treatment. The difference is not statistically significant (p=0.53).

In the present study irrespective of H.pylori eradication. duodenal ulcer healing rate at 4 weeks after completion of respective therapy with triple drug regimen (i.e. at 6 weeks) and dual drug regimen (i.e. at 10weeks) is 95.31% and 100%. The difference is not statistically significant (p=0.14).

The present study has many strengths. The sample size relatively fair when compared to other studies of anti H.pylori regimens. It is of its first kind of study comparing the dual drug regimen of 6weeks with standard triple drug regimen of 2 weeks. Apart from H.pylori eradication rates it also addressed the effects of patients personal habits like smoking, alcohol and patients' co-morbid health conditions like Diabetes and Systemic hypertension on H.pylori eradication rates. It

addressed and compared the frequency of medication side effects with both regimens. Another main strength is addressing gastric and duodenal ulcer healing rate that too in both H.pylori eradication successful as well as unsuccessful patients.

### CONCLUSIONS

H.pylori eradication rate with Amoxicillin plus Omeprazole dual drug regimen for 6 weeks is inferior to Clarithromycin based triple drug regimen for two weeks. Peptic ulcer healing rate at four weeks after end of treatment is similar with both triple drug regimen and dual drug regimen. Ulcer healing rate either gastric or duodenal is 100% with both triple drug regimen & dual drug regimen when they could result in pylori eradication. H.pylori eradication rates with both dual and triple drug regimens are more in diabetics when compared to non diabetics.

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