

Original Article

TO COMPARE THE EFFICACY OF HYBRID THERAPY VERSUS CONVENTIONAL TRIPLE REGIMEN IN HELICOBACTER PYLORI INDUCED GASTRITIS

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ABSTRACT

Background: To compare the efficacy of Hybrid therapy versus conventional triple regimen in H.pylori induced gastritis

Material and methods: It was a Randomized control trial 170 patients fulfilling the selection criteria were enrolled in the study from OPD of Hijaz hospital Lahore and the Department of Gastroenterology, Jinnah Hospital Lahore. 85 cases were given Hybrid therapy (Group-A) and 85 were given conventional triple regimen (Group-B). Informed consent was obtained.

Results: Demographic information (name, age, and sex) were taken. The mean age was 40.43 ± 17.01 years in the Hybrid therapy group and 42.99 ± 12.98 years in the conventional triple regimen group. In group A, 62% of cases had ages less than 45 years, and 37.6% had ages 45 years or above. In group B, 68.2% cases had an age less than 45 years and 31.8% of cases had an age of 45 years and above. In group A, 50.6% of cases were male and 49.4% were female. In group B, 72.9% of cases were male and 27.1% were female. In group A, 58.8%, 22.4%, and 18.8% of cases had low, middle and high socioeconomic status respectively. In group B, 57.6%, 29.4 and 13% of cases had low, middle and high socioeconomic status respectively.

In the Hybrid therapy group, eradication was achieved in 91.8%. In conventional triple regimen, eradication was achieved in 62.4% cases (p-value=0.00).

Conclusions: Eradication achievement was significantly more common with Hybrid therapy than the conventional triple regimen. Hybrid therapy was significantly more effective than the conventional triple regimen in all ages, genders, and socioeconomic groups.

Key Words: Helicobacter pylori, Infection, Peptic ulcer

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INTRODUCTION

Helicobacter pylori infection affects more than half of the world's population. There is a definite correlation between this chronic infection and peptic ulcer disease as it causes atrophic and metaplastic changes in the stomach mucosa.¹ The usual route of infection is fecal-to-oral.²

It can also cause other gastric disorders, including chronic active gastritis, stomach cancer, and mucosa-associated lymphoid tissue (MALT) lymphoma. H pylori infection produces numerous biochemicals that stimulate the gastric parietal cells (resulting in HCL production) and ECL cells (which secrete gastrin and somatostatin). H. pylori repress D cells while G cells are stimulated. H Pylori infection is more prevalent in underdeveloped countries. The clinical picture varies, although most patients develop superficial gastritis, a minority develop nodules and ulcers.² This infection is one of the most common causes of dyspepsia. On diagnosis, Standard triple therapy is

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suggested for 14 days, followed by acid-suppressive treatment (H₂-receptor antagonists, or PPIs) for 6 weeks. The test of choice to document eradication is urea breath test (UBT) or stool antigen test. The patient must discontinue acid suppressive drugs for 2-4 weeks before having these tests.

Triple therapy consists of double antibiotics, such as amoxicillin-metronidazole or amoxicillin-clarithromycin plus a PPI (proton pump inhibitor) for 14 days. Antibiotic resistance is becoming more common, notably with clarithromycin. The eradication rate of triple therapy in real practice is 10% lower than in research trials. Following the failure of first-line therapy, several rescue therapies have been suggested, although they still have a failure rate $\geq 20\%$. With a typical length of 14 days (7 days + 7 days), hybrid therapy is divided into two phases: dual therapy (PPI and amoxicillin) and quadruple /concomitant therapy (PPI, amoxicillin, clarithromycin and metronidazole/tinidazole). The drug dose was PPI, amoxicillin 1 g, clarithromycin 500 mg, and metronidazole/tinidazole 500 mg, all administered twice daily.³⁻⁶

The sequential administration of hybrid treatment may account for its remarkable efficacy. Pretreatment with amoxicillin is related to a decreased bacterial load. As a result, the organisms' sensitivity is changed, and they respond better to clarithromycin and tinidazole later.⁷⁻⁹ To prove this notion, further data is necessary.

As indicated, H. pylori-induced gastritis is now exceedingly common. This study aims to find out the role of hybrid therapy in treating H. pylori infection compared with conventional triple therapy in the Pakistani population. Due to variations in demographic profile, differences in antibiotic resistance patterns, and variations in disease presentations, the study is of paramount importance in defining the best treatment. We may introduce it as a first-line treatment in place of a conventional regimen if sufficient results are obtained in favor of this therapy in managing H. pylori gastritis.

MATERIAL AND METHODS

A Randomized Control Trial was conducted in the OPD of the Hijaz Hospital Lahore and the Medical Unit II/Gastroenterology Department of the Jinnah Hospital Lahore. The study lasted for a year (08-June-2021 to 09-Jun-2022). The study's sample size was 170 patients (with a 2% margin of error and a 95% confidence level). Non-probability, purposive sampling was the technique adopted. Patients diagnosed with H. Pylori-Induced Gastritis (based on the histology of a stomach biopsy or the findings of H. Pylori stool antigen test/Urea breath test) were included in the study. Males and females between the ages of 18 and 70 were included. Patients with a history of stomach surgery, an allergy to study medications, a history of using antibiotics within the preceding two weeks, a history of receiving H pylori eradication therapy within the previous five years, a history of using probiotic products within the previous month, a history of taking bismuth, an H₂ receptor antagonist, PPIs, or antifungal medications during the previous two weeks, as well as those who did not sign an informed consent form, were all excluded from the study

Total number of 170 individuals with H. pylori gastritis were enlisted following ethical committee permission and patient informed consent. A total of 85 patients in the two groups—Group A or Group B—were randomly assigned to them. Randomization was carried out using sealed envelopes numbered and labelled with the names of the groups. The diagnosis was made using the H. Pylori stool antigen. Group A underwent hybrid therapy, while group B received a conventional triple regimen. A stool test for H. Pylori antigen was also carried out to determine eradication, 4 weeks following the end of therapy (a "Negative" result was interpreted as a sign of treatment success). The pertinent data was entered into a specifically created proforma.

SPSS 25 was used to analyse all of the gathered data. The mean and standard deviation, like age, were determined for quantitative/numerical data. For qualitative

data like gender and eradication rate, frequency and percentage were calculated. The chi-square test was used to compare the eradication rate of H. Pylori between the two groups as the primary outcome measure. To account for the effect modifiers, data were stratified by age, gender, and socioeconomic status. A p-value of 0.05 or less was regarded as significant.

RESULTS

The mean age was 40.43 ± 17.01 years in group A and 42.99 ± 12.98 years in group B. In group A, 62% of cases had age < 45 years and 37.6% had age ≥ 45 years. In group B, 68.2% cases had age < 45 years and 31.8%

cases had age ≥ 45 years. In group A, 50.6% of cases were male and 49.4% were female. In group B, 72.9% of cases were male and 27.1% of cases were female. In group A, 58.8%, 22.4%, and 18.8% of cases had low, middle, and high socioeconomic status respectively. In group B, 57.6%, 29.4 and 13% of cases had low, middle, and high socioeconomic status respectively. In group A, eradication was achieved in 91.8%. In group B, eradication was achieved in 62.4% cases (p-value=0.00). Stratification of eradication rate was done with regards to age group, gender and socioeconomic status and p-values were depicted in respective tables (Table # 1, 2).

Table-1: Distributions of variable with frequency and percentage

Variable	Study Group		p-value	
	Group A	Group B		
Age group	Less than 45 years	53(62.4%)	58(68.2%)	0.42
	Equal or more than 45 years	32(37.6%)	27(31.8%)	
Gender	Male	43(50.6)	62(72.94%)	0.003
	Female	42(49.4%)	23(27.06%)	
Socioeconomic Status	Low	50(58.8%)	49(57.6%)	0.42
	Middle	19(22.4%)	25(29.4%)	
	High	16(18.8%)	11(13%)	
H pylori Eradication	Yes	78(91.8%)	53(62.4%)	0.00
	No	7(8.2%)	32(37.6%)	

Table-2: Age group, Gender, Socioeconomic status wise stratification of Eradication rate

Variable	Study Group	Eradication		p-value	
		Yes	No		
Age group	Less than 45years	Group A	47	6	0.02
		Group B	41	17	
	Equal or more than 45years	Group A	31	01	0.00
		Group B	12	15	
Gender	Male	Group A	41	02	0.00
		Group B	39	23	
	Female	Group A	37	05	0.01
		Group B	14	09	
Socioeconomic status	Low	Group A	46	04	0.2
		Group B	41	08	
	Middle	Group A	17	02	0.00
		Group B	06	19	
	High	Group A	15	01	0.01
		Group B	06	05	

DISCUSSION

Treatment regimens for *H. pylori* are becoming less successful due to rising antibiotic resistance, particularly to clarithromycin.¹⁰⁻¹⁵ According to certain studies, triple therapy's clinical success rate is lower than in research trials by 10%.¹³⁻¹⁵ Therapies that are effective, safe, and easy to follow are therefore crucial. Hsu et al. presented the hybrid therapy in 2011 have generated considerable interest. This regimen is highly successful (cure rates exceeding 90%) in several Italian studies; several guidelines have recommended this treatment.¹⁶⁻¹⁸ After the first line of treatment didn't work, several rescue therapies have been developed. The eradication rate in our study was 91.8% for the hybrid therapy group and 62.4% for the conventional therapy group (p-value = 0.00). Hybrid therapy cure rates differ greatly between regions and populations while maintaining excellent compliance and safety. There are still several challenges that require more research. The limited data shows that the main factor influencing the effectiveness of hybrid therapy is the combined resistance to clarithromycin and metronidazole. It was also unclear how long hybrid therapy should last and how much PPI dosage should be used. Only a few studies have examined the variables affecting the efficacy of concomitant therapy, and the effects of some of these variables, such as P450 isoenzyme 2C19 gene polymorphism, are still unknown.¹⁹⁻²¹ It is necessary to assess how much a hybrid therapy will cost. Analysis is made more difficult due to variations in patient recruitment, *H. pylori* detection techniques, dosages, duration, frequency, the relationship to dietary intake, and background antibiotic resistance. Like sequential and concomitant therapies, hybrid therapy is equally effective, compliant, and safe.

CONCLUSIONS

Hybrid therapy is a highly effective treatment choice for management of *Helicobacter pylori* infection. Future research on a larger

sample size ought to concentrate on eradication's efficiency, safety and cost-effectiveness in regions with high levels of antibiotic resistance.

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Conflict of interest: None

AUTHOR'S CONTRIBUTION

AAB: Conceived idea, main researcher and supervisor as well

NA: Data collection and critical review

MG: Proofreading

IM: Review critically

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