

RESEARCH ARTICLE

Comparative Study of efficacy of Ilaprazole and Omeprazole in Patients with Acid Peptic Disease

Sri Roja. I*, E. Shanmugapriya, Dr. P. Shanmugasundaram

Department of Pharmacy Practice, School of Pharmaceutical Sciences, Vels University (VISTAS), Chennai, Tamil nadu-600117

*Corresponding Author E-mail: sahanashree2012@gmail.com

ABSTRACT:

Aim and objective:

The aim of the study was to compare and evaluate whether there is any difference in efficacy between ilaprazole and omeprazole in patients with acid peptic disease with symptoms.

Methods and materials:

A prospective randomized open label comparison was conducted in 100 patients in which 50 patients of group-A received ilaprazole and 50 patients of group-B received omeprazole who visited the in-patients of general medicine department over a period of 6 months.

Results:

Among 100 patients, the highest numbers of patients were from the age group of 18-30 years. Most commonly diagnosed conditions were peptic ulcer, duodenal ulcer, gastro-esophageal reflux disease and gastritis. The efficacy analyses were based on 100 patients. At week 4, 54% of male patients and 46% of female patients of group-A treated with 5 mg ilaprazole, 10 mg ilaprazole and 46% of male patients and 54% of female patients of group-B treated with 20 mg omeprazole once daily respectively had reduced heart burn, acid reflux symptoms and ulcers healed. The majority of patients (>80%) became asymptomatic after 4 weeks treatment in group-A compared with patients in group-B.

Conclusion:

The present study showed that ilaprazole is more effective than omeprazole and low dose of ilaprazole offers a gastric acid inhibition when compared to routine dose of omeprazole.

KEYWORDS: Ilaprazole, omeprazole, symptom relief, proton pump inhibitor, acid peptic disease.

INTRODUCTION:

Hyper secretion of acid and acid related diseases are the most common problems in many countries. The hypersecretion of acid may lead to changes in the gastric epithelium, but in more serious cases it may lead to erosions of the esophagus which can result in metaplasia and death [1-3]. The inhibition of hyper secretion with a proton-pump inhibitor or H2 receptor antagonist is the mainstay of treatment of the pathology and symptoms of gastroesophageal reflux disease [4].

The quality of life for patients suffering from acid peptic disease have been greatly improved by these two therapies; however while still taking the drugs, there is an increasing number of patients that have experienced recurrent disease [5].

Proton pump inhibitors are one of the most commonly prescribed and highly effective classes of drugs that are widely used in the treatment of acid peptic diseases including gastric and duodenal ulcer, gastro esophageal reflux disease and Zollinger-Ellison syndrome [6-9]. Proton pump inhibitors selectively and irreversibly inhibit the gastric H⁺, K⁺-ATPase which is the final step in acid secretion. In terms of chemical structure, all proton pump inhibitors consist of Benzimidazole ring

and a pyridine ring, but they vary in specific side ring substitution^[10].

Recently, a new Benzimidazole compound, Ilaprazole {2-[[[4-methoxy-3-methyl)-2-pyridinylmethylsulfinyl-5-(1H-pyrrol-1-yl)-1H-benzimidazole, CAS 172152-36-2}}, designated also as IY81149 was synthesized at Il-Yang Pharmacy Co. (Seoul, Korea) and is presently developed by Livzon Pharmaceutical Group, Inc. (Zhuhai, China)^[11-13]. Preclinical research found that ilaprazole had a more prolonged half-life and higher suppression of gastric acid secretion in a dose-dependent manner. A comparative pharmacodynamic study on patients with gastroesophageal reflux disease reported that ilaprazole, at a dose of 5 mg, provided gastric pH control comparable with the use of 20 mg omeprazole, and at doses of 10 and 20 mg it was found to have a more powerful and long-lasting acid suppressant effect than omeprazole at a dose 20 mg^[14]. There have been several clinical trials comparing ilaprazole and other proton pump inhibitors in the treatment of duodenal ulcer, which showed that ilaprazole had a high 4-week healing rate^[15, 16].

Hence the present prospective study was conducted with the aim of comparing and evaluating the efficacy of ilaprazole and omeprazole in patients with acid peptic disease in the department of general medicine in-patients at ESI hospital, Ayanavaram.

METHODOLOGY:

Study site:

The study was carried out in the general medicine in-patient department of ESI hospital, Ayanavaram.

Study population:

The study population consists of 100 patients satisfying inclusion criteria.

Inclusion criteria:

Patients were eligible if they

- Were 18-65 years of age
- Both male and female in-patients diagnosed with acid peptic disease
- Willing to participate.

Exclusion criteria:

Patients were ineligible if they

- Were unwilling to co-operate
- Were female patients who were breast feeding, pregnant
- Had a cancerous or complex ulcers.

Study period:

The study was carried out from October 2016 to March 2017 (6-months). The study was approved by the

institutional review board. An oral and written consent was obtained from the patients before their participation in the study.

Study design:

It was a prospective randomized open label comparison. The relevant data on clinical symptomatology, diagnosis and treatment were recorded on a customized data collection sheet and rate of symptomatic healing at week 4 was assessed by using four point scale and SF-12 questionnaires.

Parameters for evaluation:

The parameters included were age and gender wise distribution, marital status, social history of acid peptic disease between groups, symptoms, H.Pylori infection, co-morbidities and healing rate of population after drug administration.

RESULTS:

The study attended to compare the efficacy of ilaprazole and omeprazole in patients with acid peptic disease. Among 100 prescriptions, 50 prescriptions were collected from in-patients who received ilaprazole and 50 from in-patients who received omeprazole.

1) Gender wise distribution:

Among 100 patients, 54% of male patients and 46% of female patients were enrolled in group-A. And 46% of male patients and 54% of female patients were enrolled in group-B.

Table-1:

Gender	Group-A (n=50)	Percentage %	Group-B (n=50)	Percentage %
Male	27	54%	23	46%
Female	23	46%	27	54%

2) Age wise distribution:

In this study, the highest number of patients (41%) from the age group of 18-30 years, 20% of population belongs to 31-45 years, 16% of population belongs to 46-55 years and 23% of population belongs to 56-65 years.

Table-2:

Age	No. of patients (n=100)	Percentage%
18-30	41	41%
31-45	20	20%
46-55	16	16%
56-65	23	23%

3) Age wise distribution between groups:

In group-A, among 50 patients, 44% of population belongs to the age group of 18-30 years, 20% of population belongs to 31-45 years, 16% belongs to 46-55 years and 20% belongs to 56-65 years of age. In group-B, among 50 patients, 38% of population belongs to 18-30 years, 22% belongs to 31-45 years, 16% belongs to 46-55 years and 24% belongs to 56-65 years of age.

Table-3:

Group-A	No. of patients (n=50)	Percentage%	Group-B	No. of patients (n=50)	Percentage%
18-30	22	44%	18-30	19	38%
31-45	10	20%	31-45	11	22%
46-55	8	16%	46-55	8	16%
56-65	10	20%	56-65	12	24%
MEAN±SD	12.5±5.54			12.5±4.03	

4) Based on marital status:

Among 100 patients, 70% were married and 30% unmarried in group-A. And 64% were married and 36% were unmarried in group-B.

Table-4:

Marital status	Group-A (n=50)	Percentage %	Group-B (n=50)	Percentage %
Married	35	70%	32	64%
Unmarried	15	30%	18	36%

5) Based on social history of acid peptic disease between groups:

In this study, among 50 patients in group-A, 12% of population were alcoholics, 20% were smokers, 16% were both alcoholic and smoker and 52% of population had no history. Among 50 patients in group-B, 8% were alcoholics, 14% were smokers, 20% were both alcoholic and smoker and 58% had no history.

Table-5:

Social history	Group-A	Percentage%	Group-B	Percentage%
Alcoholic	6	12%	4	8%
Smoker	10	20%	7	14%
Alcoholic+ Smoker	8	16%	10	20%
No history	26	52%	29	58%
MEAN±SD	12.5±7.921		12.5±9.759	

6) Based on symptoms:

In this study, among 50 patients in group-A, 64% of patients are with heart burn and 36% of patients are with acid reflux symptoms. Among 50 patients in group-B, 60% of patients are with heart burn and 40% of patients are with acid reflux symptoms.

Table-6:

Symptoms	Group-A (n=50)	Percent age%	Group-B (n=50)	Percentage %
Heart burn	32	64%	31	60%
Acid reflux	18	36%	20	40%
MEAN±SD	25±7		25±5	

patients in group-B, 46% of patients are with H. Pylori positive and 54% are negative.

Table-7:

Infection	Group-A	Percent age%	Group-B	Percentage %
Positive	20	40%	23	46%
Negative	30	60%	27	54%
MEAN±SD	25±5		25±2	

7) Based on H. Pylori infection:

Among 50 patients in group-A, 40% of patients are with H. Pylori positive and 60% are negative. Among 50

8) Based on co-morbidities:

Among 50 patients in group-A, 24% are with diabetes mellitus, 30% are with hypertension and 16% are with cardiovascular disorders. Among 50 patients in group-B, 36% are with diabetes mellitus, 22% are with hypertension and 10% are with cardiovascular disorders.

Table-8:

Co-morbidities	Group-A	Percentage%	Group-B	Percentage%
Diabetes mellitus	12	24%	18	36%
Hypertension	15	30%	11	22%
Cardiovascular disorders	8	16%	5	10%
MEAN±SD	11.6±2.86		11.3±5.31	

9) Healing rate of population at week 4 after drug administration:

At week 4 of after drug administration, 81% of male patients and 82% of female patients were healed in group-A. And 56% of male patients and 66% of female

patients were healed in group-B. Patients treated with ilaprazole in group-A shown to have better healing rate when compared to patients treated with omeprazole in group-B.

Table-9:

Gender	Group-A (n=50)	Percentage%	Group-B (n=50)	Percentage%
Male (n=27)	22	81%	(n=23) 13	56%
Female (n=23)	19	82%	(n=27) 18	66%
MEAN±SD	20.5±1.5		15.5±2.5	

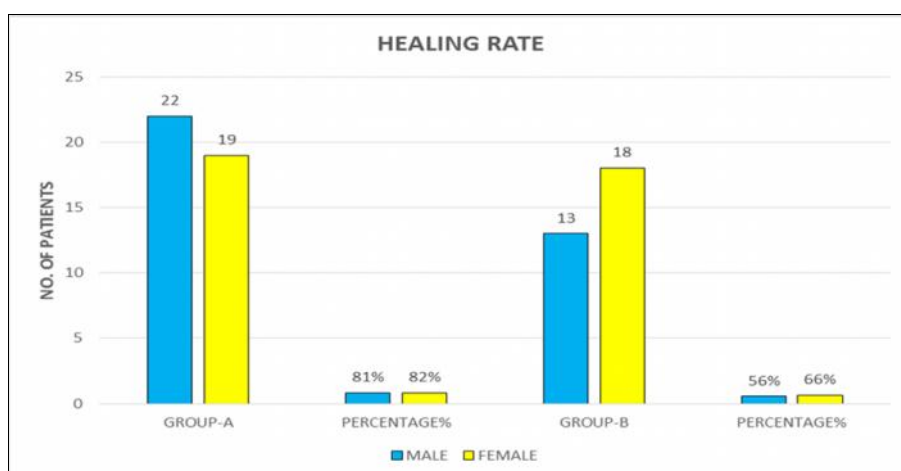


Figure-9: Healing rate of population at week 4 of after drug administration

DISCUSSION:

The present study evaluates the efficacy of ilaprazole and omeprazole in patients with acid peptic disease carried out over a period of six months (October 2016-March 2017). The majority of population (41%) belongs to the age group of 18-30 years. Acid secretion is an essential component of digestive process and provide both concentrated acid enzyme to aid in the breakdown of foodstuffs in to components that can be absorbed in the intestine [17]. But in some patients this process does not work properly leading to hypersecretion of acid causing symptomatic pain and discomfort [18]. When hypersecretion occurs for long period of times, the risk of erosion of epithelia and internal bleeding increases dramatically. Wide variety of agents have been proposed that either block the histamine receptors or target the acid extrusion pump in an effort to conflict the effects of hypersecretion [19]. The symptoms of reflux esophagitis such as heart burn have been demonstrated to markedly impair quality of life in these patients [20]. A multicentric trial conducted by Wang et al in 2011 confirmed ilaprazole as an effective gastric acid suppressor; gastric acid suppression increased with the increasing dose of ilaprazole, viz. 5 mg, 10 mg, 20 mg [21]. Two registered trials also evaluated the efficacy in terms of symptom relief through a graded score technique which served as a secondary end-point. Wang et al [22] and Ho et al [23] concluded that a majority of patients (>75%) became asymptomatic after treatment with ilaprazole.

In the present study we compared the efficacy of ilaprazole and omeprazole in patients with acid peptic disease. Out of 100 patients, 50 patients were treated with ilaprazole in group-A and 50 patients were treated with omeprazole in group-B. The majority of population (41%) belongs to the age group of 18-30 years of age. 70% of population were married in group-A and 64% of population were unmarried in group-B. 40% of population are with H. Pylori positive in group-A and

46% of population are with H. Pylori negative in group-B. In group-A, 24% of population are with diabetes mellitus, 30% are with hypertension and 16% are with cardiovascular disorders. In group-B, 36% are with diabetes mellitus, 22% are with hypertension and 10% are with cardiovascular disorders. In group-A, 81% of male patients and 82% of female patients were healed at week 4 of after drug administration. In group-B, 56% of male patients and 66% of female patients were healed at week 4 of after drug administration.

The administration of ilaprazole was most effective when compared with omeprazole; because ilaprazole has been shown to have a faster onset of anti-secretory activity than omeprazole.

Recently proton pump inhibitors has been also used for the diagnosis of gastroesophageal reflux disease, not only in the patients with non-erosive reflux disease [24, 25], but also in patients with atypical gastroesophageal reflux symptoms [26, 27].

LIMITATIONS:

The study was carried out for a period of 6 months. Further, the number of patients were low and the study was restricted only to one hospital.

CONCLUSION:

Overall the study results conclude that ilaprazole 5 mg and 10 mg may be more effective than omeprazole 20 mg daily for rapid relief of symptoms in patients with acid peptic disease.

Ilaprazole provided significantly better pH control over 24 hours and during evening and overnight hours compared with omeprazole, which may translate to greater relief of night-time heart burn in the clinical setting for patients with gastric acid-related disorders.

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CONFLICT OF INTEREST:

No conflict of interest is declared.

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