Clinical Trial of Efcid (Himcocid) in Patients of Acid Peptic Disease

Rangamani, K.,
Professor of Medicine, Bowring and Lady Curzon Hospitals, Shivajinagar, Bangalore, India.

ABSTRACT
Fifty patients in the age group of 18-60 years from the medical wards of Bowring and Lady Curzon Hospital were enrolled for the study. Out of 50 patients 30 were males and 20 were females. All the patients were subjected to upper gastrointestinal evaluation by endoscopy except for 3 patients who did not agree to undergo endoscopic evaluation. The diagnosis was based on clinical symptoms and endoscopic findings. Of the 47 patients who underwent endoscopic examination, 31 had gastritis with reflux esophagitis, 11 had peptic ulcers and 5 had portal hypertensive gastropathy with oesophageal varices. Efcid syrup was given to all the patients at a dose of 10-15 ml thrice daily for a period of 4 weeks. The drug was well tolerated and there were no adverse effects. In all the 50 patients the response was good with significant symptomatic relief. A majority of the patients were on monotherapy, only Efcid syrup.

Key words: Efcid, Hyperacidity, Acid peptic disease

INTRODUCTION
Gastritis is characterised by inflammation of the gastric mucosa. It has many causes such as infection with Helicobacter pylori, an autoimmune (Type A Gastritis) and chemical gastritis resulting from ingestion of non-steroidal anti-inflammatory drugs or a reflux of the duodenal contents into the stomach. Gastrooesophageal reflux disease (GERD) results from regurgitation of gastric content into the oesophagus. It is an acid-peptic disorder that has a significant impact on both health and the quality of life. Patients who have uncomplicated gastroesophageal-reflux disease typically present with heartburn and acid regurgitation.

Another common cause of upper gastrointestinal symptoms is non-ulcer dyspepsia (NUD). The pathophysiology of this condition has been poorly characterised and its optimum treatment is uncertain. As gastric acid plays a major role in the pathophysiology of this disease, acid neutralisation/suppression has emerged as the cornerstone of GERD therapy. Most of the patients who call on physicians also suffer from peptic ulcer. Peptic ulcer is a breach in the mucosa of the stomach or duodenum, which penetrates the muscularis mucosa. Peptic ulceration is also influenced by pepsin, gut acid, H. pylori infection and ingestion of NSAIDs. Erosions in these cases are less than 3-5 mm in diameter and do not penetrate muscular mucosa. It has been estimated that 40% of adverse drug reactions affect the gastrointestinal tract, which highlights the contribution of drug-induced gastritis in acid peptic diseases.

Antacids, prokinetics and gastric antisecretory agents are the principal drugs currently used to treat gastritis in conjunction with life-style modifications. Due to the short duration of buffering action, antacids are primarily used as self-medication for temporary relief of
symptoms. Heartburn is also common and the sufferers attribute symptoms to various lifestyle events, including diet and stress. In all these cases antacid usage is the commonest mode of therapy.

Antacid therapy is one of the therapeutic options in addition to withdrawal of the offending drug. Efcid, an herbomineral antacid is used to treat gastritis and GERD. Efcid has a gastro-protective effect by virtue of its versatile modes of action in gastritis and other related gastrointestinal diseases. Calcium from calcium containing antacids and milk enhance the integrity of gastrointestinal mucosa and mucous, as it is the natural linker agent of these structures, which strengthens their defence function. Efcid contains many naturally occurring calcium and magnesium salts, which are known to neutralise gastric acid. This study was undertaken to study the effects of Efcid in patients suffering from gastritis, acid peptic diseases and nonulcer dyspepsia. The period of study was from Feb. 1, 2000 to April 30, 2000.

PATIENTS AND METHODS

This study was designed as a prospective open study in relieving the signs and symptoms of gastritis and acid peptic diseases. The study included patients reporting to the medical O.P.D. at Bowring and Lady Curzon’s Hospital attached to Bangalore Medical College, Bangalore. Patients diagnosed with gastritis, gastric/duodenal ulcer, heartburn and congestive gastropathy due to chronic liver disease were included in the study.

The primary requirement for inclusion was the clinical features suggestive of gastritis or acid peptic disease for 1 - 2 weeks. In addition, patients with a past history of haematemesis or malena were also included in this study.

Patients who were on aluminium antacids, or hepatoprotective drugs such as silymarin, other herbal preparations, H2 blockers and proton pump inhibitors one month prior to entry into the study were excluded from the study. Elderly patients and pregnant women were also excluded from the study.

All the patients underwent a complete physical examination. Relevant medical history and demographic details were recorded with special reference to drugs used, smoking habits and usage of alcoholic beverages. All the patients were administered Efcid at a dose of 2 - 3 teaspoonful (10-15 ml) three times a day after meals for four weeks.

The clinical profile of all the patients at the beginning of the treatment (counted as day 0) was recorded. The severity of the clinical signs and symptoms such as pain, nausea, vomiting, flatulence, abdominal discomfort and fatigue were noted. Loss of appetite was graded on a 4 point severity scale (absent, mild, moderate and severe) on entry and then at every follow-up, i.e. at the end of the 1st, 2nd, 3rd and 4th weeks.

Laboratory investigations were carried out in all the patients, which included complete blood count and Hb%. Stool tests for ova, cyst and occult blood was carried out. Upper gastrointestinal tract endoscopy was done in 47 cases with 3 patients refusing to undergo the procedure. Biopsies were done to study histology and detect H. pylori infection to exclude...
gastric cancer. A repeat endoscopy was done to ascertain healing after 4 weeks of treatment and in some cases it was done after 6 weeks.

Patients were required to note the treatment at the end of study on a 4-point scale (excellent, good, fair and poor). The investigator’s assessment of the treatment with regard to the efficacy and tolerance was made on a 4-point scale (excellent, good, fair and poor) at the end of the study. Any adverse event either reported by the patient or observed by the investigator was recorded in the record form. Statistical analyses of the results were done and the significance was compared to the base line.

RESULTS

Of the 50 patients included in the study, all the patients completed the study and were found suitable for analysis. As per the diagnosis by endoscopy, 31 were diagnosed with gastritis, 11 had acid peptic disease, 5 had gastropathy with portal hypertension in secondary to chronic liver disease and 3 had dyspepsia (Table 1). There was a significant reduction in the severity scores for abdominal pain, flatulence, nausea and vomiting at the end of 3 weeks of treatment as compared to the base line. The percentage reductions for abdominal pain was 60% and 80% at the third and fourth weeks of treatment respectively, and for flatulence and vomiting was 70% and 85% respectively. The severity of nausea, loss of appetite and fatigue was significantly less after 2 weeks of treatment (Table 2).

The reduction observed in all the symptoms was statistically significant. At the end of the study symptoms disappeared naturally and continued antacid therapy was not required. Endoscopy was repeated in a majority of cases, and the results showed a significant improvement in healing.

It was observed that there was excellent or good response in 86 – 87% of the patients after treatment. At the end of the study, the investigators rated efficacy and tolerance of treatment as excellent to good in 90% of the patients.

As far as the adverse events were concerned, two cases of diarrhoea were reported. However this side effect did not warrant discontinuation of treatment and the overall excellent tolerability profile of the 2 patients was not affected (Tables 3 and 4).
DISCUSSION

Acid-related diseases, such as gastroesophageal reflux disease (GERD), have a significant impact on healthcare. As a result, healthcare providers must devise ways to limit expenditure while providing high-quality patient care. Although the goals of therapy are the same in both traditional and managed care environments, optimal cost-containment strategies depend heavily on the specifics of payment and risk arrangements involved. Cost-saving strategies involving drug therapy are often based on the assumption that treatments with lower acquisition costs are the most cost effective. In case of gastritis treatment, the efficacy of acid-suppression therapies should also be considered. In addition, efficacy should be a major consideration in therapy choice because recurrence and complications as a result of ineffective therapies can negatively affect the patients’ quality of life and increase the overall cost of healthcare\(^8\). Studies have shown that people who had received at least one prescription of cimetidine, famotidine, nizatidine, ranitidine, lansoprazole or omeprazole acid-suppressing drugs, had a substantial increase in risk of developing pancreatitis\(^9\).

We took up the study of Efcid as it is a safe herbomineral preparation. Efcid is a suspension comprising of Varatika which is a sea (marine) shell rich in carbonate of calcium\(^ {10} \), Dugdhapashana rich in magnesium silicate\(^ {11} \), Moutika sukti a purified form of pearl oyster is rich in calcium carbonate\(^ {12} \) and an anti-ulcer herb known as *Glycyrrhiza glabra*\(^ {13} \).

Efcid has proved to be an effective and well tolerated drug in the management of gastritis, heartburn and acid peptic disease. It has a high standard of efficacy and safety in both gastritis and in ulcer therapy and provides good symptomatic relief in all patients.

Few patients were given *H. pylori* eradication treatment in whom *H. pylori* infections were detected. In NSAIDs related gastritis and ulcers withdrawal of the drug and antacid suspension gave good result.

CONCLUSION

Thus, it can be concluded that Efcid is effective in relieving symptoms of gastritis and acid peptic disease. Pain relief was considerate in the first two weeks itself. No patients complained of any adverse events. Efcid could become the mainstay in the management of gastritis and acid peptic disease.

REFERENCES


