

## LANSOPRAZOLE IN THE TREATMENT OF ACUTE PEPTIC ULCER DISEASE

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### ABSTRACT

This is an open study conducted by the gastroenterology department of Ayub Medical College, Abbottabad. The aim was to study the effect and tolerance of lansoprazole in peptic ulcer disease, in a dose of 30 mg nocte. A total of 15 patients completed the trial, (Oesophageal ulcers 4, Gastric ulcers 4, Duodenal ulcers 7). Assessment was made clinically and endoscopically. The healing rate at the end of 6 weeks was 100%. The drug was well tolerated with no side effects. Most of these patients had taken H<sub>2</sub> receptor antagonists without benefit. In conclusion lansoprazole is an effective and safe drug in healing acute peptic ulcers and is well tolerated.

### INTRODUCTION

Peptic ulcer disease is an extremely common problem seen in almost a third of all gastroenterological referrals.<sup>1</sup> H<sub>2</sub> receptor antagonists have been used in the management of the disorder, since 1972, introduced by Black et al,<sup>2</sup> This revolutionized the management of peptic ulcer disease, but recently the trend seems to be changing from the use of H<sub>2</sub> receptor antagonists to the direct inhibition of the parietal cell H<sup>+</sup> K<sup>+</sup> ATPase, the last link in the pathway of acid secretion. This allows the clinician to accomplish maximum degree of acid suppression, which is necessary for some of our patients, specially for patients with reflux oesophagitis. It has also been shown that there is a direct relationship between the degree of acid suppression and the rate of ulcer healing.<sup>3</sup> Beside omeprazole, a newly developed proton pump inhibitor, lansoprazole has been introduced in our market. The aim has been to study the effect and tolerability of lansoprazole in acute peptic ulcer disease.

### MATERIAL AND METHOD

Patients with symptoms of peptic ulcer disease were endoscoped. Those with oesophageal ulcer, gastric ulcer and duodenal ulcer were included in the trial. Pregnant, lactating females, patients with serious concurrent illness likely to effect the study (e.g. cardiac, renal and hepatic illnesses, and malignant gastrointestinal pathology were excluded from the trial. No other antiulcer drug was permitted during the trial. No other antacid/aniflatulent was allowed except gelucil whenever necessary. A total of 20 patients were enrolled for the study, out of which 15 patients completed the trial. The duration of the study varied from 2 to 8 weeks depending on the indication and its severity. Lansoprazole 30 mg nocte was the drug used and assessment was made symptomatically and endoscopically. Those patients whose ulcers did not heal in 8 weeks were considered as treatment failures. Endoscopy was performed with an Olympus X Q 30 gas-troduodenoscope, after spraying the throat with 4% lignocaine and an I/V injection of diazepam (dose according to patient requirement). An informal consent was obtained from all the patients.

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## ASSESSMENT SCHEDULE

For each indication patients were asked according to the following schedule.

### A). DUODENAL ULCER:

- |                       |   |
|-----------------------|---|
| i) First assessment   | First day, Symptomatically and endoscopically.                |
| ii) Second assessment | After 2 weeks of therapy, Symptomatically and endoscopically. |
| iii) Third assessment | After 4 weeks of therapy Symptomatically and endoscopically.  |
- Two weeks thereafter if required.

### GASTRIC ULCER AND REFLUX OESOPHAGITIS WITH ULCER

- |                       |  |
|-----------------------|--|
| i) First assessment   | First day symptomatically and endoscopically.                |
| ii) Second assessment | After 4 weeks of therapy symptomatically and endoscopically. |
| iii) Third assessment | After 6 weeks of therapy symptomatically and endoscopically. |
| iv) Fourth assessment | After 8 weeks of therapy symptomatically and endoscopically. |

## RESULTS

Of the 20 patients, 15 patients completed the trial (7 males and 8 females). The age of the patients ranged from 28-62 years, with a mean age of  $45 \pm 5.67$  years. Five patients failed to complete the trial as they were unwilling to undergo repeated endoscopy. In all the 15 patients who completed the trial there was complete healing of the respective lesions. In the Oesophageal ulcer group the healing rate was 2 in 4 weeks and 2 in 6 weeks. (Table I) Of these one had already taken H<sub>2</sub> receptor antagonist and failed to respond, and one had taken both H<sub>2</sub> receptor antagonist as well as omeprazole. With H<sub>2</sub> receptor antagonist there was no response at all, with omeprazole there was improvement but within a few weeks of stopping treatment, the symptoms recurred; with lansoprazole he remained symptomless. In the gastric ulcer group (Table II) the healing rate was 3 in 4 weeks and one in 6 weeks, of these one had already taken an H<sub>2</sub> receptor antagonist but had failed to respond. In the duodenal ulcer group (Table III), the healing rate was 6 in 2 weeks and one in 4 weeks. Again three of these patients had taken full course of an H<sub>2</sub> receptor antagonist and had not responded to it.

No side-effect was reported by any of these patients.

**PATIENT CHARACTERISTICS AND HEALING RATES**

**TABLE I      ESOPHAGKAL ULCER**

|   | Age in years | Sex | Habits | Healing rate in weeks | Previous therapy                               |
|---|--------------|-----|--------|-----------------------|--|
| 1 | 50           | M   | Smoker | 6                     | H <sub>2</sub> receptor antagoist + Omeprazole |
| 2 | 45           | M   | non    | 4                     | Antacids                                       |
| 3 | 34           | F   | non    | 6                     | Antacids                                       |
| 4 | 32           | M   | Smoker | 4                     | Antacids                                       |

**TABLE II      GASTRIC ULCER**

|   | Age in years | Sex | Habits | Healing rate in weeks | Previous therapy                   |
|---|--------------|-----|--------|-----------------------|------------------------------------|
| 1 | 45           | F   | non    | 4                     | Antacids.                          |
| 2 | 35           | M   | non    | 4                     | Antacids                           |
| 3 | 50           | M   | Smoker | 6                     | H <sub>2</sub> receptor antagoist. |
| 4 | 28           | F   | non    | 4                     | Antacids                           |

**TABLE III      DUODENAL**

|   | Age in years | Sex | Habits     | Healing rate in weeks | Previous therapy                   |
|---|--------------|-----|------------|-----------------------|------------------------------------|
| 1 | 28           | M   | Smoker     | 2                     | Antacids.                          |
| 2 | 35           | F   | non        | 2                     | Antacids                           |
| 3 | 50           | M   | non        | 4                     | Antacids.                          |
| 4 | 40           | M   | Oral snuff | 2                     | H <sub>2</sub> receptor antagoist. |
| 5 | 62           | F   | non        | 2                     | H <sub>2</sub> receptor antagoist. |
| 6 | 60           | M   | Oral snuff | 2                     | Antacids                           |
| 7 | 40           | F   | non        | 2                     | Antacids                           |

**DISCUSSION**

Peptic ulcer disease is a multifactorial disease and acid secretion is not the sole factor in the pathogenesis, but the decrease in the gastric acid secretion with anti-secretory agents constitutes

the primary therapeutic approach and there is a definite relationship between the degree of acid suppression and the rate of ulcer healing and relief of symptoms.

Lansoprazole is a relatively new proton pump inhibitor with a potent effect on gastric acid secretion. It inhibits the secretion of gastric acid over a 24-hour period more effectively than H<sub>2</sub> receptor antagonist and even omeprazole<sup>4</sup>. Similarly, a greater number of gastric ulcers heal with lansoprazole than with H<sub>2</sub> receptor antagonists<sup>5,6</sup>. Lansoprazole is highly effective in the treatment of reflux oesophagitis with healing rates similar to omeprazole and the healing rate and symptom relief are much better than H<sub>2</sub> receptor antagonist after a 4 weeks of therapy<sup>7,8</sup>. Lansoprazole produced almost 100% suppression of gastric acid after an evening dose and 92% suppression with a morning dose.

Lansoprazole has no significant side-effects, none were noted in our study, even otherwise rare, occurring in 0.5 - 8.6% of patients<sup>9</sup>. These are diarrhoea, nausea, headache and dermatologic reactions. Serum gastrin levels and enterochromaffin like cell density rose slightly during treatment with no ill effect, in short term therapy<sup>10</sup>. Both omeprazole and lansoprazole induce the cytochrome P450 Mono-oxygenase system, but are unlikely to have any clinical effect. Theophylline plasma levels should be measured in the absence of a desired clinical effect. There is no significant effect on other endocrine secretion. No sexual impairment occurs with its use. Our study, though small, suggests that lansoprazole is highly effective in peptic ulcer disease with 100% healing rate and is well tolerated.

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