A PROSPECTIVE, RANDOMIZED, CLINICAL TRIAL TO COMPARE THE EFFICACY AND TOLERABILITY OF PANTOPRAZOLE IN THE TREATMENT OF DUODENAL ULCER

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SUMMARY

Pantoprazole is a new substituted benzimidazole which inhibits gastric H+ K+ ATPase. In this prospective, randomized clinical trial, pantoprazole 40mg once daily was compared with omeprazole 20mg once daily in the treatment of duodenal ulcer. Endoscopy was repeated after 2 weeks of treatment. The primary aim was ulcer healing. Unhealed patients were given further 2 weeks of treatment and endoscopy performed at the end. After 2 weeks, 40/50 (80%) patients in the pantoprazole group and 26/50 (52%) patients in the omeprazole group had healed completely (p<0.05). After 4 weeks, 47/50 (94%) patients in the pantoprazole group and 39/50 (78%) patients in the omeprazole group had healed completely (p<0.05). Both treatments were well tolerated. We conclude that pantoprazole is more effective than omeprazole in the treatment of duodenal ulcers.

INTRODUCTION

Pantoprazole is a new substituted benzimidazole which inhibits gastric acid secretion by acting upon H+ K+ - ATPase, the final step in acid secretion. Pantoprazole is a potent antisecretory agent and has been shown to be well tolerated by patients in different clinical trials. H2 receptor antagonists were the mainstay of treatment for duodenal ulcers until the introduction of substituted benzimidazoles. However, the latter proved to be superior to H2 receptor antagonists in the treatment of duodenal ulcers. The optimum dose of pantoprazole in this indication has been shown to be 40mg once a day. This study was conducted to compare the efficacy and tolerability of 40mg pantoprazole once a day with 20mg omeprazole once a day in the treatment of duodenal ulcer.

MATERIAL AND METHODS

This study was a prospective, randomized, clinical trial, conducted in 2 centres of Peshawar: Alkhidmat Hospital and Rahim Medical Centre. Informed consent was taken from the patients. Patients entered in the trial were of either sex, aged 16 years or above, with endoscopically diagnosed duodenal ulcers. Patients were excluded from the trial, if they had reflux esophagitis (Savary Miller grade II and above), severe concomitant disease, pregnant women, or history of allergic drug reactions.

After the initial endoscopic examination, patients were randomized to one of the two treatment protocols on 1:1 basis i.e. Group-I tab pantoprazole 40mg. OD for 2 weeks; and group -II cap omeprazole 20mg OD for 2 weeks. Both the groups were given
H. pylori eradication treatment (of clarithromycin 500mg, BD and amoxicillin 1gm BD for one week) on the reported association of H. pylori with duodenal ulcers. Patients were re-endoscoped after 2 weeks treatment. Healing was defined as the complete re-epithelization of the ulcer crater. Patients with healed ulcers received no further treatment, but patients whose ulcers had not healed, received the study treatment for a further 2 weeks. The safety of the drugs was assessed by the occurrence of adverse events.

Statistical Analysis

Baseline characteristics and obtained results of both study groups were analyzed by Student’s t test and chi-square test. P value of less than 0.05 was considered to be statistically significant.

RESULTS

One hundred patients entered the trial: 50 patients in each group. All the patients completed the trial, none of them were dropped out of the trial. Both the groups were comparable regarding their baseline characteristics (table 1).

**Efficacy**

The healing rates are presented in figure 1. After 2 weeks treatment, complete healing of duodenal ulcers had occurred in 40(80%) patients in the pantoprazole group and only 26(52%) patients in the omeprazole group. The difference between the two treatment groups was statistically significant (p<0.05). Patients with healed ulcers received no further treatment, but patients whose ulcers had not healed, the treatment was continued for further 2 weeks. Thus after 4 weeks, complete healing of duodenal ulcers had occurred in total of 47(94%) patients in the pantoprazole group and total of 39(78%) patients in the omeprazole group. The difference between the two treatment groups was statistically significant (p<0.05) again.

**Safety**

Both treatments were well tolerated. Adverse events were reported by 6/50(11%) patients in the pantoprazole group and by 7(14%) patients in the omeprazole group. Diarrhoea, constipation, and asthenia were the most frequently reported events. None of these patients discontinued the treatment; the complaints were of mild nature and transient duration.

| TABLE - I |
|---------------|---------------|----------------|
| **BASE LINE CHARACTERISTICS OF PATIENTS** | **Pantoprazole (n=50)** | **Omeprazole (n=50)** |
| Male/Female | 40/10 | 42/8 | p>0.05 |
| Mean age (yrs) | 40 | 39 | p>0.05 |
| No of ulcers: | | | |
| 1 Ulcer | 41 | 38 | p>0.05 |
| 2 Ulcers | 7 | 9 | p>0.05 |
| > 2 ulcers | 2 | 3 | p>0.05 |
| Cigarette smokers | 23 | 20 | p>0.05 |
| Snuff | 44 | 45 | p>0.05 |
FIGURE 1: HEALING RATES AT 2 WEEKS, & 4 WEEKS

<table>
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<th>Healing Rate % PTS</th>
<th>P&lt;0.05</th>
<th>40</th>
<th>26</th>
<th>P&lt;0.05</th>
<th>47</th>
<th>39</th>
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<tr>
<td>2 weeks</td>
<td></td>
<td></td>
<td></td>
<td>4 weeks</td>
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**DISCUSSION**

This is the first study on pantoprazole in duodenal ulcers from Pakistan. In this study, healing rates of 80% and 52% were observed after 2 weeks of treatment in the pantoprazole and omeprazole group respectively. After 4 weeks, healing rates rose further to 94% and 78% in the two groups respectively. The difference between the results is statistically significant (p<0.05), suggesting that pantoprazole is more effective than omeprazole in the treatment of duodenal ulcers and its associated symptoms. In most of the cases in pantoprazole group (80% vs 52%), healing occurred after 2 weeks, and even, results with 2 weeks therapy with pantoprazole i.e. (80%) were better that 4 weeks therapy with omeprazole i.e. (78%). Both treatments were generally well tolerated.

Many trials have been performed to evaluate the efficacy of 40mg pantoprazole and 20mg omeprazole in the treatment of duodenal ulcers. The average healing rates with pantoprazole were 76% after two weeks of treatment, and 96% after 4 weeks of treatment. Administration of 20mg omeprazole over 2 to 4 weeks in duodenal ulcer resulted in the average healing rates of 69% and 93% in the literature, respectively. When directly compared with pantoprazole, the healing rates of 20mg omeprazole after 2 weeks treatment (65% - 74%) compare well with the data found in the literature 69%, but after 4 weeks treatment 89% - 91%. They are slightly lower than literature data 93%. The healing rates of pantoprazole after 2 weeks 71% and after 4 weeks 96% seem to be slightly higher, and compare well with the healing rates of 40mg omeprazole 72% and 97% after 2 and 4 weeks respectively.

In conclusion, pantoprazole 40mg once daily is more effective than omeprazole 20mg once daily in the treatment of duodenal ulcers, but as well tolerated as omeprazole.

**REFERENCES**


