Effect of Single Nocturnal Dose of Pirenzepine Versus Ranitidine in Duodenal Ulcer

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Abstract

Of 50 consecutive patients with endoscopically proven duodenal ulcers, 25 each were open randomly assigned to treatment with either a single nocturnal dose of pirenzepine 100 mg or ranitidine 300 mg for four weeks. The groups were well matched for age and duration of symptoms, but there were significantly more smokers (15 vs 8) in the pirenzepine group. Ulcer healing rate as confirmed by endoscopy after four weeks of treatment was 84% in the pirenzepine group and 96% in the ranitidine group (p > 0.01). A single nocturnal dose of pirenzepine 100 mg for four weeks as the treatment of duodenal ulcer appears to be as effective as a single nocturnal dose of ranitidine 300 mg for the same period.

Key words: Duodenal ulcer, nocturnal dose, ranitidine, pirenzepine.

Introduction

The current trend in the treatment of duodenal ulcer is to administer a single night time dose. Despite the lack of control during the day time, duodenal ulcers will heal if nocturnal acidity is decreased. Single nocturnal dose of an histamine H2 receptor antagonist is now established as the optimal regimen in the treatment of peptic ulcer.2,3 and day time administration seems to be unnecessary.4

Howden et al5 studied the effect of single nocturnal doses of pirenzepine on overnight gastric secretion and found 100 mg as the optimum dose which would limit the side effects and hence could be useful in the treatment of duodenal ulcer.

The aim of the present study was to compare prospectively in an open randomized fashion a single nocturnal dose of pirenzepine 100 mg with a single nocturnal dose of ranitidine 300 mg in the healing of duodenal ulcer. This to our knowledge is the first report on the clinical efficacy of single nocturnal dose of pirenzepine in the healing of duodenal ulcer.

Material and Methods

Fifty consecutive patients with endoscopically proven duodenal ulcers were randomly assigned to open treatment with either a single nocturnal dose of pirenzepine 100 mg or ranitidine 300 mg for four weeks. At the start of treatment all patients were symptomatic and had not received treatment with histamine H2 receptor antagonists for the previous three months.

The pirenzepine group consisted of 23 males and two females, aged 19-49 (mean ± SD 33.2 ± 7.2) years. The average duration of ulcer history was 3.5 ± 2.8 years. The ranitidine group had 23 males and two females, aged 20-60 (mean ± SD 34.2 ± 7.2) years. The average duration of ulcer history was 4.7 ± 3 years.

Basal clinical evaluation was performed to exclude other medical illnesses and to record smoking habits and alcohol intake. The diagnosis was established by endoscopy and endoscopy was repeated after 4 weeks of treatment on all patients.

The Wilcoxon rank sum test was used to compare differences between the two groups, and chi squared test to compare healing rates, at a significant probability value of 5%.

Results

There was no statistical difference in age distribution or duration of symptoms between the two groups. The number of smokers was significantly greater in the pirenzepine group (15 vs 8; p < 0.01). There was no history of alcohol intake in either group. All except one patient were Muslims.

At the end of two weeks all patients with healed ulcers were asymptomatic. The endoscopic healing rate after four weeks of treatment was 84% (21/25) with pirenzepine as compared to 96% (24/25) with ranitidine; the difference was not significant (p > 0.01).

Dryness of mouth was noted in only one patient taking pirenzepine; no other side effects were seen.

Discussion

Our study was based on the importance of reducing the nocturnal acid secretion in the therapy of duodenal ulcer. The observation that a single night time dose of cimetidine could prevent duodenal ulcer relapse suggested that a large nocturnal dose might be an effective primary treatment for duodenal ulcer.6 Gledhill et al confirmed this by showing that a single night time dose of 800 mg cimetidine was as effective as 400 mg twice daily in reducing mean 24-hour intragastric acidity. Moreover, the nocturnal acid secretion was significantly better controlled with the night time dose. Similar results were obtained by comparing a single night time dose of 300 mg ranitidine with 150 mg twice daily; the single nocturnal dose inhibited nocturnal gastric acid secretion.
acidity by 85% and 24-hour intragastric acidity by 62%.

Howden et al3 examined the effect of nocturnal administration of pirenzepine 100 mg or 150 mg on gastric secretion. The mean nocturnal acidity was decreased by approximately 53% and mean gastric acid output by 67% with both doses. Dry mouth was noted in only those receiving the 150 mg dose. The authors concluded that pirenzepine 100 mg was the optimum nocturnal dose which could be conveniently given without significant side effects.

Smoking habits have been shown to adversely affect the healing rates in duodenal ulcer.7 Although there was a significantly higher number of smokers in the pirenzepine group, the endoscopic healing rate with this drug was not statistically different from that with ranitidine in our study. Hence pirenzepine (100 mg) and ranitidine (300 mg) as single nighttime doses seem to be equally efficient at four weeks in healing duodenal ulcers. A single nocturnal dose of pirenzepine 100 mg may thus be an efficient, convenient and safe regimen for the treatment of duodenal ulcer.

References