Omeprazole Vs Ranitidine in the Healing of Duodenal Ulcer*

Pages with reference to book, From 111 To 112

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Abstract

To assess the comparative efficacy of omeprazole 20 mg in the morning versus ranitidine 150mg twice a day, in the healing of duodenal ulcer, 43 endoscopicolly verified cases were randomly allocated to 2 or 4 weeks (if ulcer did not heal at 2 weeks) treatment. Two cases were excluded due to deviation from the protocol. Of 21 cases treated with ameprazale 15 (71%) healed at two weeks and all (100%) at 4 weeks. Similarly of 20 cases treated with ranitidine, 14 (70%) healed at 2 and 18 (90%) at 4 weeks (P=NS). Two patients who did not heal with ranitldlne, when crossed aver to ameprazale healed at 4 weeks. Na significant difference in the rate of pain relief, clinical or laboratory parameters are adverse effects were noted in either group. Bath the drugs were well tolerated and were patent healer of duadenal ulcer; but ameprazole appears to be superior in the healing of resistent ulcers (JPMA 43: 111, 1993).

Introduction

Omeprazole is a substituted benzimidazole derivative that acts selectively on the parietal cells[1]. It inhibits the final step in the formation of hydrochloric acid by blocking the enzyme H^+, K^+- ATPase[2] and thereby accelerates the healing of duodenal ulcer3. The comparative trials conducted in Europe have demonstrated a success rate exceeding92% at four weeks, suggesting that the anti-secretory potency correlates directly with the ulcer healing[3,4]. The efficacy and safety of this drug is still to be evaluated in our patients. The present study was conducted to evaluate the comparative efficacy, safety and tolerance of omeprazole with that of ranitidine in the healing of duodenal ulcer.

Patients and Methods

From the out-patients of PMRC Research Centre, Jinnah Postgraduate Medical Centre, candidates with endoscopically verified duodenal ulcer were studied. Patients between 18-80 years of age having at least one active duodenal ulcer of >5 mm size were included in the study. Pregnant and lactating mothers, patients treated with full-dose of anti-ulcer drugs for more than 3 days during the previous 2 weeks and non-steroidal antiinflammatory drugs, those with pyloric stenosis, concurrent gastric or prepyloric ulcer, bleeding ulcers, renal and hepatic disease and those who underwent gastric surgery except for simple closure were excluded. Patients were randomly assigned to two weeks of treatment with either ranitidine 150 mg twice daily or omeprazole 20 mg once daily in the morning. The patients were given diary cards to record the pain score (mild, moderate and severe) during day and night time. The patients were seen after two weeks (±1 day) for clinical assessment and endoscopy to see the healing (i.e., complete epithelialization of the ulcer site). Therapy was continued for further two weeks in non-healers and similar assessment was done at four weeks (± 2 days). Patients who did not heal at 4 weeks were crossed over to the other drug to see the healing at two and four weeks. The number of tablets or capsules returned were recorded. Patients who did not take the medicine for three days or more were regarded as dropouts. The patients were allowed but not encouraged to take antacid. Laboratory tests done before enrolment and at the completion of trial included hemoglobin, hematocrit, leukocyte total and differential and platelet counts. Urinalysis included specific gravity, pH, albumin

sugar, bile, RBC and pus cells. The statistical methods used were x^2 test and student \'t\' test.

Results

Initially 43 cases (35 males and 8 females) entered the study, of these two were excluded (one due to deviation from the protocol and other lost to follow-up). Finally, 41 patients (21 on omeprazole and 20 on ranitidine) completed the study.

Table. Comparison of the demographic characteristics of the two groups of patients.

	Omeprazole	Ranitidine
Total cases	21	20
Sex: Male/Female	18/3	15/5
Age: Range (yrs.)	18-70	19-65
Mean ± SD	38±13	42±15
Duration of disease		
Mean ±SD	52±86	49±48
Non-smokers	10	14
Smokers (1-10)	9	4
(10-20)	2	2
Previous surgery (simple closure)	3	2
Previous G.I. bleeding	6	4
No. of ulcer: Single	18	18
Multi	3	2
Ulcer size (mm)		
<10	18	17
>10	3	3

Table compares various demographic characteristics of patients in two treatment groups. Of 21 cases treated with omeprazole 15 (71%) healed at 2 weeks and all (100%) at 4 weeks. Similarly out of 20 cases treated with ranitidine 14 (70%) healed at 2 weeks and 18 (90%) at 4 weeks. Two cases who failed to heal after 4 weeks ofranitidine therapy were crossed over to omeprazole; of these one healed at 2 weeks and other at 4 weeks of treatment. Pain relief was earlier with omeprazole 6±4 days as compared to ranitidine 8±5 days but the difference did not reach statistical significance (N.S.). In the former group 16(76%) patients became pain free during the first week vs 11 (55%) in the latter group (N.S.) and all the patients on omeprazole became pain free at 2 weeks (Figure 1 and 2).

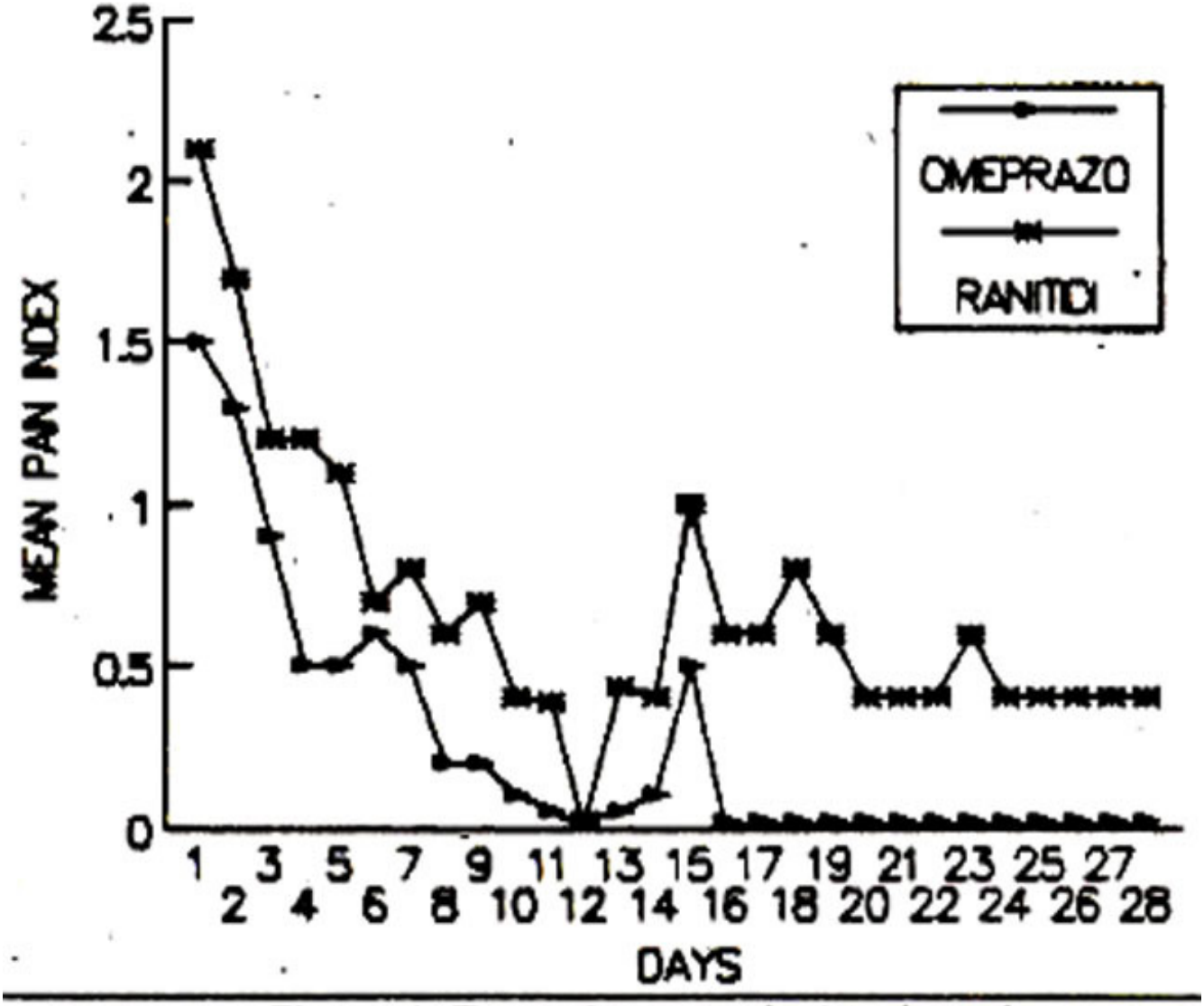

Figure 1. Day pain score during 4 weeks.

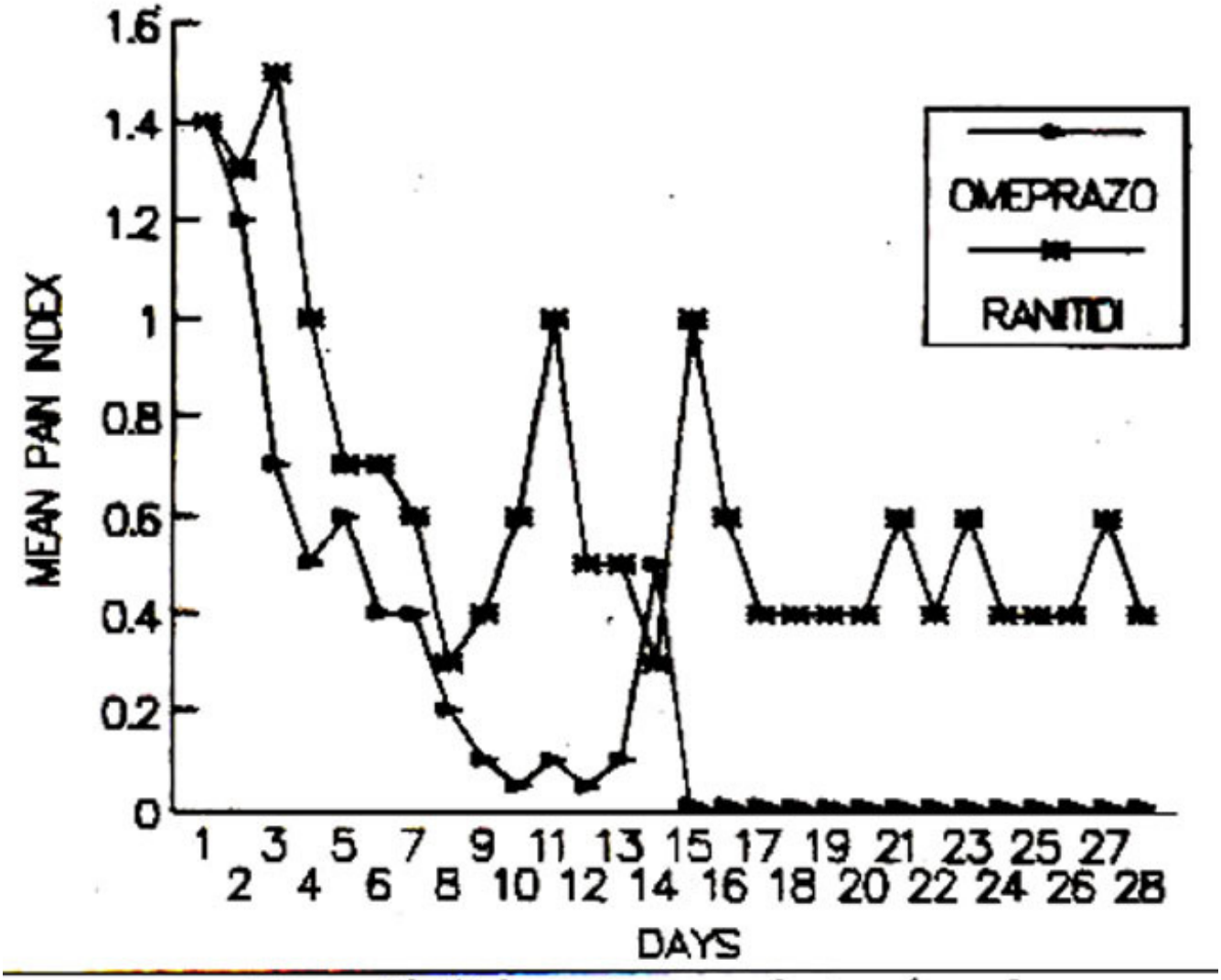

Figure 2. Night pain score during 4 weeks.

No adverse effects were noted in either treatment group.

Discussion

Comparative efficacy of omeprazole and ranitidine in the healing, pain relief and reducing relapse rate of duodenal ulcers has been studied, using the optimal doses which were shown to be effective but not causing complete suppression of gastric secretion[5]. The present study has demonstrated that omeprazole 20 mg once daily in the morning is effective in the healing of duodenal ulcer and is well tolerated. The healing rates of omeprazole and ranitidine were similar a 2 weeks, whereas at 4 weeks although it was numerically greater with omeprazole 100% but the difference was not statistically significant. This observation is contrary to the earlier studies showing comparatively better healing rates with omeprazole than ranitidine both at 2 and 4 weeks[6,7]. Though the healing rates observed in this trial are higher than those achieved at 2 and 4 weeks with the same drugs and dose in the trials conducted elsewhere[6,8], the reason of this difference is not readily apparent. It could be due to differences in the duration of disease and previous treatment with H2 receptor antagonists, because chronic exposure can regulate the gastric secretion up and can influence the requirement of antisecretory drugs. Two patients having large and deep ulcers, who failed to heal with ranitidine at 4

weeks healed with omeprazole showing a more potent effect in the healing of such ulcers. Similar observation was made in earlier studies, showing its potency in the healing of resistant peptic ulcers[9]. This suggests that chronic large ulcers which need higher doses or longer treatment by the conventional drugs may be benefitted with the normal doses of omeprazole due to its greater antisecretory effect. Although most patients in both groups were free of pain after 2 weeks of treatment but omeprazole relieved pain more rapidly than ranitidine. Among the omeprazole treated cases, 76% were free of pain after the first week, as compared to 55% treated with ranitidine, but the difference could not reach the significance level. In conclusion, ulcer healing and pain relief with omeprazole is similar to that of ranitidine, but omeprazole appears to be more effective in the healing of resistant ulcers.

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