

Healing and Relapse Rates of Duodenal Ulcer with Omeprazole Vs Ranitidine

Pages with reference to book, From 89 To 91

Waquaruddin Ahmed, Huma Qureshi, S. Ejaz Alam, S. J. Zuberi (PMRC Research Centre, Jinnah Postgraduate Medical Centre, Karachi.)

Abstract

The efficacy of omeprazole 20mg a day was assessed against ranitidine 150mg twice a day in the healing and relapse of duodenal ulcer. Forty three endoscopically verified cases were allocated to 2 weeks of treatment, which was extended to 4 weeks, if the ulcer persisted on day 15. Two cases were excluded due to deviation from the protocol. Of 41 evaluable cases, 21 received omeprazole and 20 ranitidine. Healing rates with omeprazole and ranitidine at 2 weeks were 71% and 70% respectively which rose to 100% and 90% at 4 weeks (N.S). There was no significant difference in pain relief in two groups. Follow-up endoscopies, in 33 healed cases revealed 100% relapse at 3 months in omeprazole and 79% in ranitidine treated cases ($P < 0.05$) (JPMA 45: 89, 1995).

Introduction

Of all anti-ulcer drugs introduced so far; omeprazole has been reported to be the most potent. It works through its antisecretory property by inhibiting H⁺, K⁺ ATPase enzyme^{1,2}. Efficacy of this drug is established on the basis of high healing and low relapse rate but scarce data is available on the frequency of ulcer relapse after cessation of the therapy³⁻⁶. The present study was done to see the healing and relapse rate of duodenal ulcer with omeprazole or ranitidine.

Patients and Methods

Adult patients with endoscopically verified duodenal ulcer seen at the PMRC Research Centre, Jinnah Postgraduate Medical Centre, were included in this study. Pregnant and lactating mothers, patients taking anti-ulcer drugs for more than 3 days during the previous 2 weeks, or on non-steroidal anti-inflammatory drugs, those with pyloric stenosis, concurrent gastric, prepyloric or bleeding ulcers, renal and hepatic disease and those who had gastric surgery except for simple closure were excluded. Patients were assigned to two weeks treatment with either ranitidine 150mg twice daily or omeprazole 20 mg once in the morning. All patients were given diary cards to record the pain score (mild, moderate and severe) during day and night and were clinically assessed and endoscoped at 2 weeks to see ulcer healing. Therapy was continued for further two weeks if ulcer did not heal and reassessment was done at four weeks (± 2 days). Patients whose ulcer persisted 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 was recorded and those skipping medicine for three or more days were regarded as dropouts; antacid intake was allowed but not encouraged. Laboratory tests done before enrollment and at the completion of trial, included hemoglobin, hematocrit, total and differential leukocyte and platelet counts. Urinalysis included specific gravity, pH, albumin, sugar; bile, RBC and pus cells. After completion of the trial no maintenance therapy was given and patients with healed ulcer were endoscoped at 1,3,6 and 9 months interval, or at the recurrence of symptoms to see ulcer relapse. The statistical methods used were X^2 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). Of 41 patients who completed the study, 21 were on omeprazole and 20 on ranitidine.

Table I. 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±S.D | 38±13 | 42±15 |
| Duration of disease | | |
| Mean±S.D | 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 |
| Multiple | 3 | 2 |
| Ulcer size (mm) | | |
| <10 | 18 | 17 |
| >10 | 3 | 3 |

Table I shows the 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 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 of ranitidine therapy were crossed over to omeprazole, of these one healed at 2 weeks and the other at 4 weeks. A total of 18 patients healed with ranitidine and 23 with omeprazole (including two crossed over patients). Four cases in each group were lost to follow-up. Pain relief was earlier with omeprazole (6±4 days) as compared to ranitidine (8±5 days) (N.S). In the former group 16 (76%) patients became painfree during the first week, vs 11(55%) patients in the later group (N.S) Figure 1 and 2).

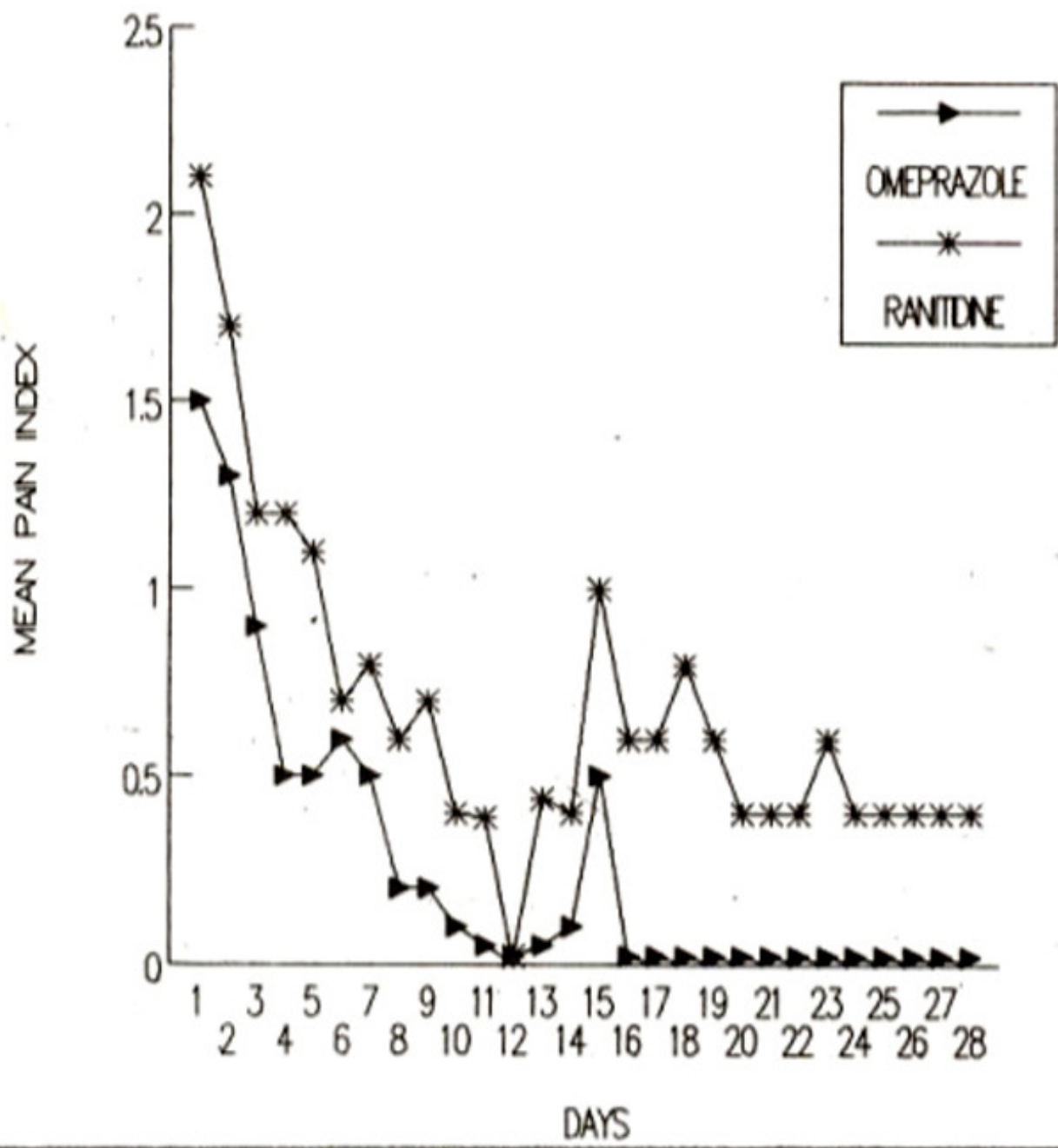


Figure 1. Day pain score during 4 weeks.

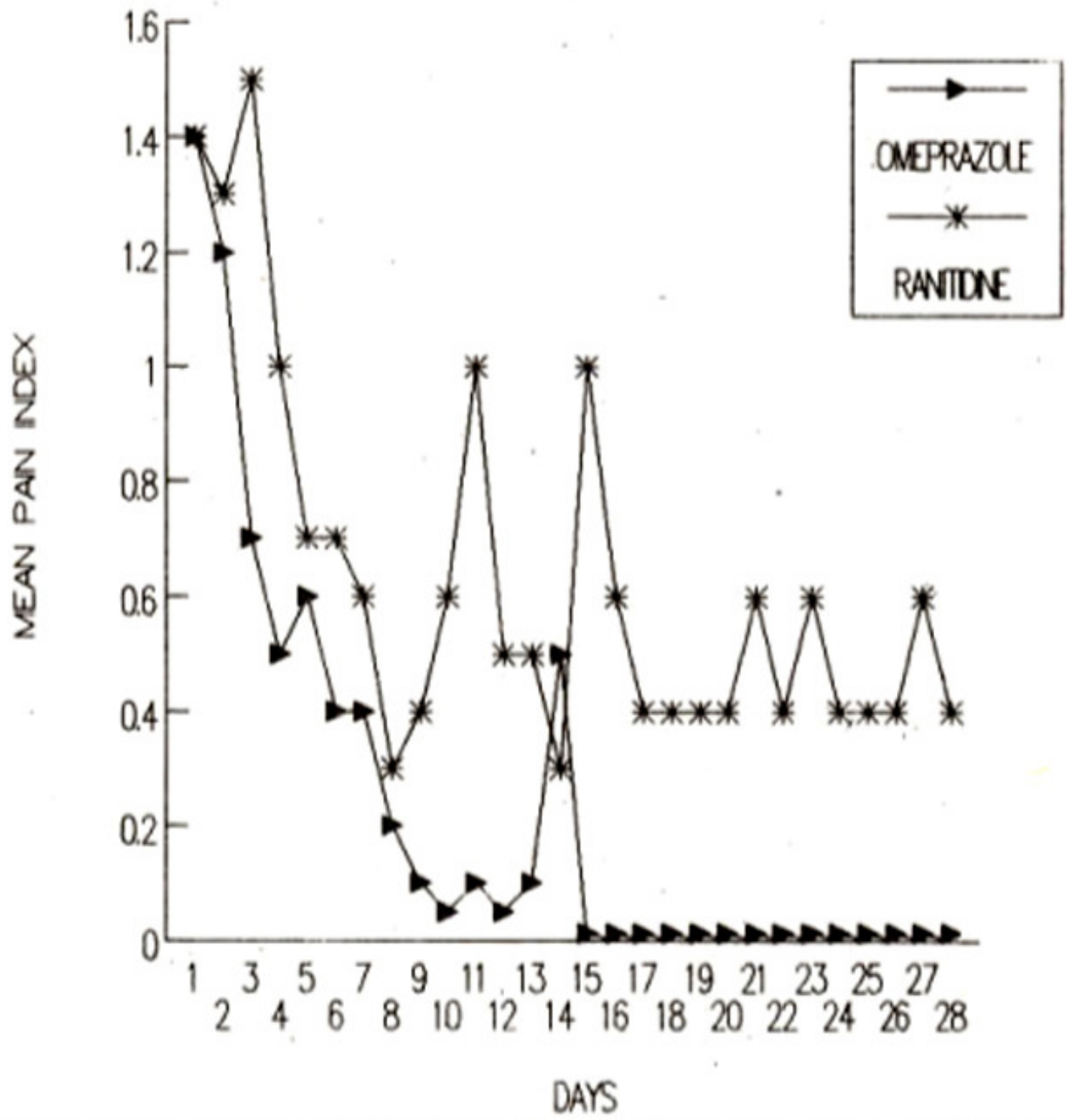


Figure 2. Night pain score during 4 weeks.

No adverse effects were noted clinically or haematologically in two treatment groups. During follow-up, of 19 patients treated with omeprazole, 15 (79%) relapsed in one month and all (100%) within three months, where as of 14 cases treated with ranitidine 10(71%) relapsed within one month and 11(79%) within three months (Table II).

Table II. Cumulative relapse rates with ranitidine and omeprazole.

| Duration | Omeprazole (19) | | Ranitidine (14) | | P-value |
|----------|-----------------|-----|-----------------|----|---------|
| | n | % | n | % | |
| 1 week | 1 | 5 | 1 | 7 | N.S |
| 2 weeks | 1 | 5 | 4 | 29 | N.S |
| 1 month | 15 | 79 | 10 | 71 | N.S |
| 3 months | 19 | 100 | 11 | 79 | P<0.05 |

Remaining 3 cases treated with ranitidine had healed ulcer till 9 months of follow-up.

Discussion

The present study showed no significant difference in the efficacy of omeprazole over ranitidine in the healing of duodenal ulcer, at 2 and 4 weeks. Similar finding has been reported earlier⁷⁻⁹. Although most of the patients (76%) treated with omeprazole were pain free after the first week as compared to those with ranitidine (55%), the overall difference in pain relief was not statistically significant. Very few studies are in agreement with this finding⁹ and most show a better response to omeprazole¹⁰⁻¹³. Two patients (one each on omeprazole and ranitidine) relapsed within first week of stopping the drug while other three ranitidine treated cases relapsed within two weeks. All these cases had recurrence of pain and were therefore endoscoped before 4 weeks. Most other relapses were seen on scheduled endoscopies done at one and three months. It is possible that actual early relapse rate might be higher because we might be missing asymptomatic relapses; even if this error is ignored the rapid relapse with both of these potent anti-secretory drugs is higher than has been reported earlier^{4,7,14,15}. The relapse rate at three months in omeprazole treated group is significantly (P<0.05) higher (100%) than that in ranitidine (79%). The possible explanation for this observation is not known but one reason might be a higher number of smokers in this group as compared to ranitidine treated cases. Such an association has been reported earlier¹⁶. Other causes for differences observed in pain relief, healing and relapse in the present study and those reported earlier could be the racial differences⁶, variable duration of disease and previous treatment with H₂ receptor antagonists¹⁷ in these groups.

Acknowledgement

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