A SINGLE NOCTE DOSE OF FAMOTIDINE IN THE TREATMENT OF DUODENAL ULCER

Pages with reference to book, From 104 To 106

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Abstract

Fifty three patients with duodenal ulcer were treated with 40 mg of famotidine at bed time. Repeat endoscopy showed healing rates of 69.8% and 83% at 4 and 6 weeks respectively. Seven patients were kept on a maintenance dose of 20 mg nocte for one year, of these one had a relapse despite taking the drug regularly. No appreciable side effects were observed with the drug (JPMA 39 104, 1989).

INTRODUCTION

Selective H2 receptor antagonists are the most frequently used drugs in the treatment of duodenal ulcer. Famotidine, a new potent H2 receptor antagonist is 20 - 160 folds more potent than cimetidine[1-9] and 3 - 20 folds more potent than Ranitidine[6,7,10]. It has a longer duration of action than cimetidine or Ranjtjdjne[1,10,11]. A good safety profile has been reported with famotidine and it does not interfere with drug metabolism or possess antiandrogenic activity[12,13]. This report presents the efficacy and safety of famotidine in the treatment of chronic Juodenal ulcer patients.

PATIENTS AND METHOD

Fifty six patients with endoscopically confirmed duodenal ulcer were included in the study. Patients younger than 18 or older than 80 years, pregnant women, lactating mothers, cases of pyloric stenosis, hiatus hernia, concomitant gastric-ulcer, neoplastic disease, acute or chronic hepatitis or cirrhosis of liver were excluded. Patients with previous history of gastric surgery (except for simple closure) and regular intake of NSAID were also excluded from the study. According to the protocol, patients with duodenal ulcer were treated with 40 mg of famotidine at bed time on outpatients basis. Each patient was given a 4 week supply of drug and a daily pain recording chart. Followup was done on 14 ± 3 and 28 ± 4 days and compliance checked with the pain score card and leftover tablets. Endoscopy was repeated after 28 ± 4 days. A further therapy for 2 weeks was given if ulcer did not heal after 4 weeks. Response in these cases was determined on a repeat endoscopy after 42 ±4 days. Nine patients who showed complete healing at 4 to 6 weeks were put on a maintenance therapy of 20 mg of famotidine nocte for one year. They were re-endoscoped at 3 monthly intervals irrespective of the presence or absence of symptoms. Pain was scored as: 0 = no pain, 1 = mild pain, 2 = moderate pain and 3 = severe pain. Healing was scored as: 2 = healed, 1 = incompletely healed, 0 = no change and I = worse. Statistical analysis was done by X2 test.

RESULTS

Of 56 patients with duodenal ulcer 3 were excluded due to noncompliance or lack of follow-up. Clinical characteristics of 53 patients are enlisted in Table 1.

TABLE I. Clinical characteristics of Patients.

Total No. of Patients	53
Sex M/F	46/7
Age (Years mean ± SD)	38.5 ± 11.9
Duration of disease (months mean ± SD)	28.4 ± 29.8
Smokers/non-smokers	31/22
Alcoholic	3
Past history of ulcer	10

Healing rates of 69.8% were seen at 4 weeks and 83% at 6 weeks. Duodenitis persisted in 37.7% and 41.5% of cases at 4 and 6 weeks respectively. Pain score evaluation (Figure)

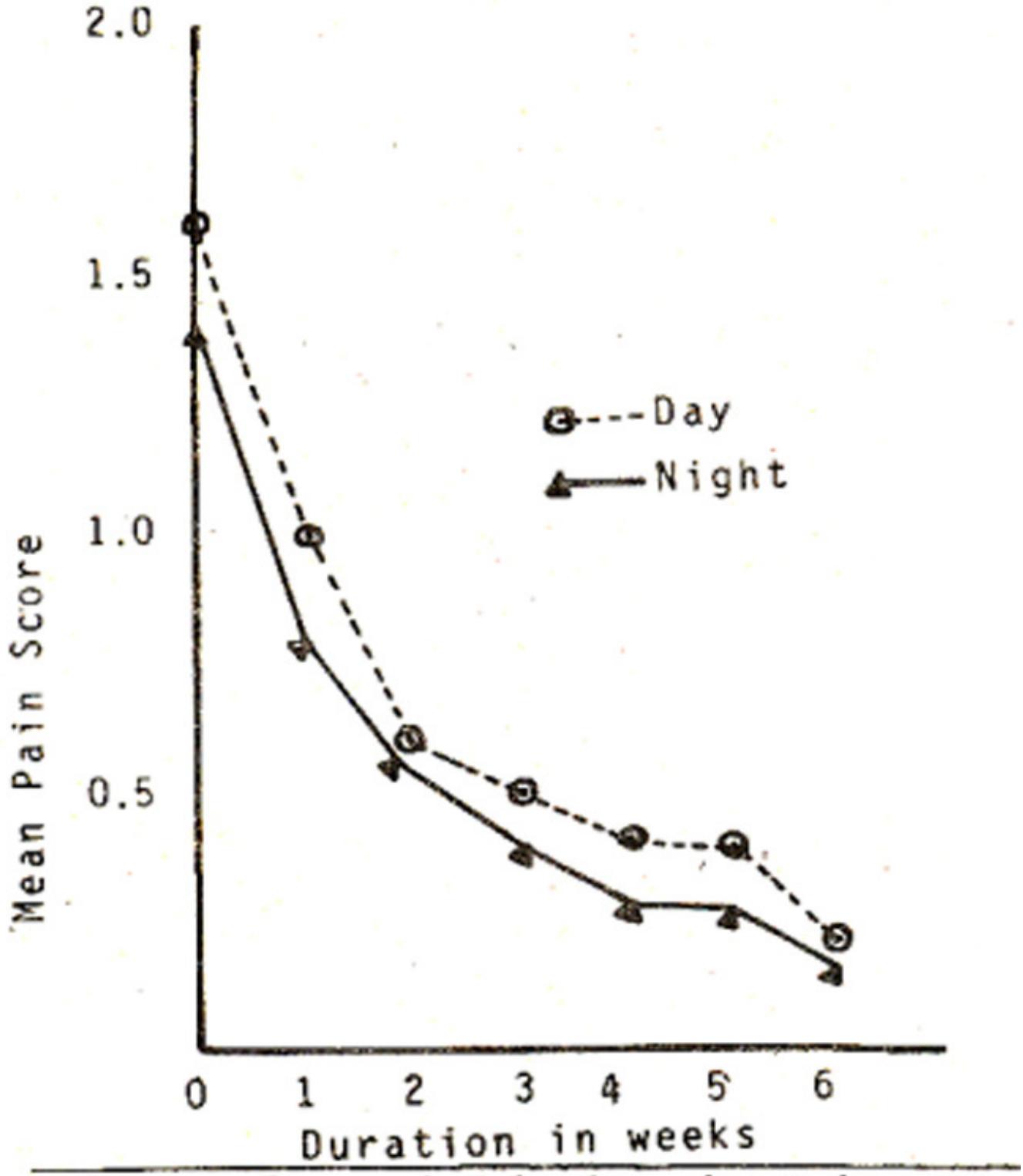

Figure. Day and night time ulcer pain score.

showed that 43% patients became pain free at the end of 2 weeks and 72% at six weeks. Thirty five percent cases with persistent ulcer also became asymptomatic with the drug therapy, six patients (13.6%) had persistent pain despite complete healing of ulcer. During long term maintenance therapy I out of 11 patients developed ischaemic heart disease, one cerebro-vascular accident and two defaulted.

Of the remaining seven cases, one had a relapse while he was taking the drug. Baseline characteristics of patients who healed and those who did not heal are shown in Table II.

TABLE II. Base line characteristics of Patients healed/not healed.

	Healed (44)	Not Healed (9)
Age (year mean ± SD)	37.8 ± 11.7	41.8 ± 12.2
Sex (M/F)	35/5	7/2
Smoking habit		
Smokers/non-smokers	26/18	5/4
Duration of disease		
(months mean ± SD)	26.6 ± 31.4	36.9 ± 17.5

Younger patients with a shorter duration of disease showed better healing rates than older patients with prolonged history of the disease, but the difference was not statistically significant. Twenty patients had oesophagitis initially, 60% of these healed after 6 weeks while the rest showed no response. Five patients developed oesophagitis while receiving the therapy. Except for vomiting, diarrhoea, allergic rashes and stomatitis in 5 cases, no other serious side effect was noted.

DISCUSSION

Present study showed that a large number of patients with duodenal ulcer heal and become asyrnptomatic when treated with famotidine at bedtime. A single dose at bedtime is recommended because nocturnal acid secretion is often regarded as the most important factor in the -pathogenesis of duodenal ulcer. Acid secretion and H+ ion concentration reach peak values at night in duodenal - ulcer patients. [14,15] Famotidine, 40 mg at bed time is known to inhibit nocturnal acid secretion by approximately 95%.[16]. The healing rates of duodenal ulcer at 4 and 6 weeks (69.8 and 83%) seen in the present study are similar (76 and 86%) to those reported by others[17], suggesting thereby that despite geographical variations and differences in eating and living habits, the response to drug therapy is almost similar the world over. This study did not show any significant differences in the healing rates for either sex and for cigarette smokers vs non-smokers. Relapse rate with famotidine was low (14%) in the present study as compared to other H2 receptor antagonists (30%) which may be due to smaller number of patients in our series. [17] The safety profile of famotidine has demonstrated no action On the cytochrome P 450 microsomal system[13] . nor does it inhibit dihydrotestosterone binding to androgen receptors[18]. Therefore famotidine was well tolerated by most of the patients with minimal side effects similar to those usually observed with other H2 receptor blockers.

ACKNOWLEDGEMENT

Financial help by Merck Sharp and Dohme is gratefully acknowledged.

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