DUODENAL ULCER: MAINTENANCE TREATMENT WITH CIMETIDINE

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Abstract

Thirty patients with endoscopically confirmed healing of duodenal ulcer were treated with cimetidine or placebo in a double blind fashion for 6 months to study the efficacy of cimetidine in prevention of ulcer relapse. Cimetidine (400 mg) or placebo were given as single bed time dose. Besides clinical features, ulcer recurrence was assessed by endoscopy. Fifteen patients received cimetidine and out of 15 in the placebo group, 14 patients completed the six months follow up period. Ulcer recurrence was noted in 3 (20%) out of 15 patients in the cimetidine group and 8 (57.1%) out of 14 in the placebo group (p<0.05).

No untoward effects were noted in any patient. (Indian J Gastroenterol 1983; 2: 81-82).

Key Words: Cimetidine, Maintenance treatment, Ulcer healing, Ulcer recurrence

Introduction

A 4-6 weeks treatment with cimetidine results in duodenal ulcer healing in about 75-85% of the cases. Such a short course of treatment, however, does not prevent further relapse of duodenal ulcer. Currently, the role of long term cimetidine treatment in prevention of ulcer recurrence is under investigation. Cimetidine maintenance therapy has been used in different dose schedules i.e. (a) 400 mg twice daily, (b) 800 mg at night and (c) 400 mg at night. Since 400 mg is able to reduce significantly nocturnal gastric acid secretion, we used this dosage. In our study, the effectiveness of maintenance treatment with cimetidine 400 mg at night has been compared with placebo in prevention of duodenal ulcer relapse over a 6 month period.

Material and Methods

A total of 30 adult patients were studied. All patients had been shown to have active duodenal ulcer at endoscopy which had healed after treatment with cimetidine (1 g/day), antacid or placebo for 4-6 weeks. Before starting these patients in the study, duodenal ulcer healing was confirmed by endoscopy. Within 2-3 days of endoscopic documentation of complete ulcer healing, patients were randomly allocated in a double blind fashion to receive either 2 tablets of cimetidine (200 mg each) or placebo at bed time. The drug and placebo tablets were of identical shape and colour.

Patients were instructed to avoid taking any other medication especially those likely to have an effect on ulcer healing. They were allowed to use antacid (Gelusil MPS 30 ml) in case of pain and a careful record was made of antacid consumption.

While on maintenance treatment, patients were followed up at monthly interval. Detailed clinical evaluation was done at every visit to assess for any ulcer recurrence and also the side effects of therapy. Amount and frequency of antacid consumption were recorded. Blood samples were collected at every visit for laboratory analysis (haemoglobin, total and differential leucocyte count, ESR, platelet count, blood urea, serum creatinine, serum bilirubin, alkaline phosphatase, and serum transaminases). Endoscopy was done at the end of 6 month treatment to find out any ulcer recurrence. If patient developed symptoms earlier, endoscopic examination was done at that time to confirm the recurrence of ulcer.

Results

Out of 30 patients, 15 received cimetidine and the remaining 15 had placebo treatment. In the placebo group, one patient failed to return for follow up after 12 weeks. The two groups were comparable in sex, age and duration of illness.

Endoscopically confirmed ulcer recurrence was noted in 3 (20%) out of 15 patients in the cimetidine group and 8 (57.1%) out of 14 patients in the placebo group. The ulcer recurrence rate was significantly less in the cimetidine group compared to placebo (p<0.05). All patients in the cimetidine group who developed ulcer recurrence had symptoms. In the placebo group, out of 8 patients having ulcer recurrence, 2 were asymptomatic.

No significant side effects were noted in either group. Laboratory evaluation did not show any evidences of bone marrow, renal or liver damage in any patient.

Discussion

The present study shows that maintenance treatment with cimetidine is effective in preventing duodenal ulcer relapse for 6 months. The relapse rate in the cimetidine group (20%) was significantly less than in the placebo group (57.1%). Similar observations have been reported by other workers. The high relapse rate in the placebo group in our study compares well with some other reports.4,6,7

There were 2 patients in the placebo group who had no symptoms but were found to have ulcer recurrence on endoscopy. There were also patients in both the groups who had symptoms but no ulcer was noted on endoscopy. Similar observations were recorded in another study where authors reported silent ulcer in 4 patients in the placebo and in 2 patients in the cimetidine group. On the other hand, there were 4 patients in the cimetidine and 1 in the placebo group in their study who had severe symptoms but no ulcer was seen on endoscopy. These observations point out the limitations of diagnosing ulcer healing or recurrence based on symptoms alone and emphasize the importance of endoscopy for assessment of results in such trials.

Different dose schedules of cimetidine have been used for maintenance treatment in various studies. Bodmar and Walan9 used 400 mg twice a day for one year and
found significant reduction in the ulcer recurrence.
Blackwood et al.¹⁰ using a single 800 mg bed time dose and Machell et al.¹² using 1 g daily dose for maintenance therapy reported similar conclusions. However, other workers have reported similar success with only 400 mg bed time dose.¹¹,¹² We used a single bed time dose because in such prolonged treatment, patient compliance is likely to be better with a single rather than multiple doses. Since, it has been shown that 400 mg of cimetidine effectively inhibits nocturnal gastric acid secretion,⁵ we used 400 rather than 800 mg of cimetidine. In fact, there is no significant difference in the relapse rate over 6 months in our study and another trial where 800 mg bed time dose was used.⁶

Cimetidine does not cure duodenal ulcer disease as shown by the frequent relapses after stopping the treatment.¹³,¹⁴ However, the present and other studies have confirmed that maintenance treatment with this drug effectively reduces the incidence of ulcer relapse. At present, there are no clear guidelines about the long term treatment with cimetidine in duodenal ulcer patients. Every patient does not require maintenance therapy. Long term prophylaxis with cimetidine should certainly be considered in patients who have a high risk of recurrence and who are not fit for surgery. The possibility that prolonged treatment with cimetidine may be an alternative approach to surgery in an uncomplicated duodenal ulcer case, needs further investigations.

References

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