Famotidine 40mg B.I.D. in the Treatment of Reflux Oesophagitis

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Abstract

To assess the efficacy of famotidine in the healing of reflux oesophagitis, 25 end oscopically proven cases were treated with famotidine 40mg B.I.D. for 6 to 12 weeks. Six patients were lost to follow-up, of the 19 cases analysed, 16 (84.2%) healed at 6 weeks and 17 (89.5%) at 12 weeks. Twelve cases (63%) became asymptomatic within six weeks of treatment. In conclusion famotidine 40 mg B.I.D. is effective in the healing of reflux oesophagitis (JPMA 45:241,1995).

Introduction

H2 receptor antagonists are less effective in the treatment of reflux oesophagitis than in peptic ulcer. Although they relieve symptoms of reflux disease but are ineffective in the healing of ulcerative and erosive oesophagitis[1-3]. High dosage of H2 receptor antagonist may be effective in the healing of reflux oesophagitis[4]. Thus the treatment became easier with the introduction of new and more potent H2 receptor antagonists. Present study was conducted to see the efficacy of famotidine in the healing of reflux oesophagitis which is still a relatively new and potent H2 receptor antagonist[5] available in our country.

Patients and Method

Patients of either sex between the age of 18-80 years who had experienced symptoms of reflux oesophagitis for more than 15 days and who were found to have moderate to severe oesophagitis on endoscopy were recruited in the study. Patients with peptic ulcer, Zollinger-Ellison syndrome, oesophageat stricture, irreducible hiatus hernia, Barrett's oesophagus, concurrent bowel disease, severe pulmonary, cardiac, cerebral, renal or liver diseases were excluded. Patients with malignancy, unstable diabetes mellitus, pregnant and lactating mothers and those who had upper G. I. surgery or taking concurrent H2 antagonists, NSAIDs, steroids, anticholinergics and antidepressants were excluded from the study. Patients meeting above mentioned criteria were clinically assessed before entering the study. Each patient was physically examined. Weight, height, heart rate and blood pressure measurements were recorded. Details of age, general medical history and history of gastro-oesophageal reflux, frequency and severity of symptoms were recorded on a standardised proforma. The degree of heartburn was assessed using a score of ito 4 for day and night separately. Score 0 no heartburn; 1 mild - but causing little or no discomfort; 2 moderately annoying but not interfering with daily activity/sleep; 3 Severe causing marked discomfort and some interference with daily activity/sleep and 4 disabling -interferes considerably with daily activity/sleep. Frequency was assessed by counting the number of episodes of daytime/night-time heartburn. Endoscopic examination of oesophagus, stomach and duodenum was performed at the entry (not more than 3 days prior to starting treatment) using Olympus 2T10 scope. The macroscopic appearance of oesophageal mucosa was graded according to the severity of disease. Grade 0 normal oesophageal mucosa; grade 1 Erythema, or diffusely red mucosa; oedema causing accentuated folds; grade 2 isolated round or linear erosions extending from the gastroesophageal junction upwards in relation to the folds. Grade 3 superficial ulceration or confluent erosions extending around the entire lumen but without stenosis; grade 4 complicated;

erosions as described above with deep ulceration, stricture and or columnar lined epithelium. Only patients with grade 2 or 3 oesophagitis were included in the study. Blood samples were collected for screening purpose at entry and at the last visit. The hematological profile included haemoglobin, haematocrit, white blood cell, differential and platelet count. Biochemical screening included measurement of urea, creatinine, alkaline - phosphatase, aspartate aimnotransferase and alanine aminotransferase. Patients received famotidine 40mg B.I.D for six weeks. total supply of medicine was given at a time, along with a score card to record the intake of drug and symptoms. They were asked to return the unused drugs and score card to check on compliance at six weeks. Endoscopy and physical examination was repeated to see healing and symptom relief. Healing was defined as complete epithelialization of erosion and/or ulcerations, i.e., grade 0 or 1. Symptom relief was defined as absence of moderate to disabling heart burn for three consecutive days prior to endoscopy. Those who failed to heal at 6 weeks, i.e., patients with grade 2 or 3 were considered as unhealed and were given another course of six weeks treatment. Clinical evaluation and endoscopy was repeated to see the final healing and symptom relief at twelve weeks. Demographic and safety data are presented for all patients who 2received study drugs. Efficacy data are presented for those who completed the study protocol. Cumulative healing rates were analysed using X2 test, stratifying by grade of oesophagitis at entry.

Results

Twenty-five cases were included in the study, six of them lost to follow-up or did not complete the study according to the porwerful requirement and were excluded from the analysis. Of the 19 cases finally analysed, 13 (68%) were males. Age ranged from 27 to 72 years with an average of 46 years. Mean height and weight were 160±12cm and 64±11kg respectively. Six patients were smokers, 2 tobacco users, 17 were tea and one coffee drinker. Thirteen (68%) patients had grade 2 and six (32%) grade 3 oesophagitis. Of the 19 cases treated with famotidine, cumulative healing was 16 (84.2%) at 6 weeks and 17 (89.5%) at 12 weeks. Two patients (10.5%) failed to heal after 12 weeks of treatment, one developed oesophageal ulcer, in other no change in oesophagitis score was observed. Mean heartburn score for day time dropped from 2.0 to 0.5 and for night from 1.5 to 0.5 (Figure)

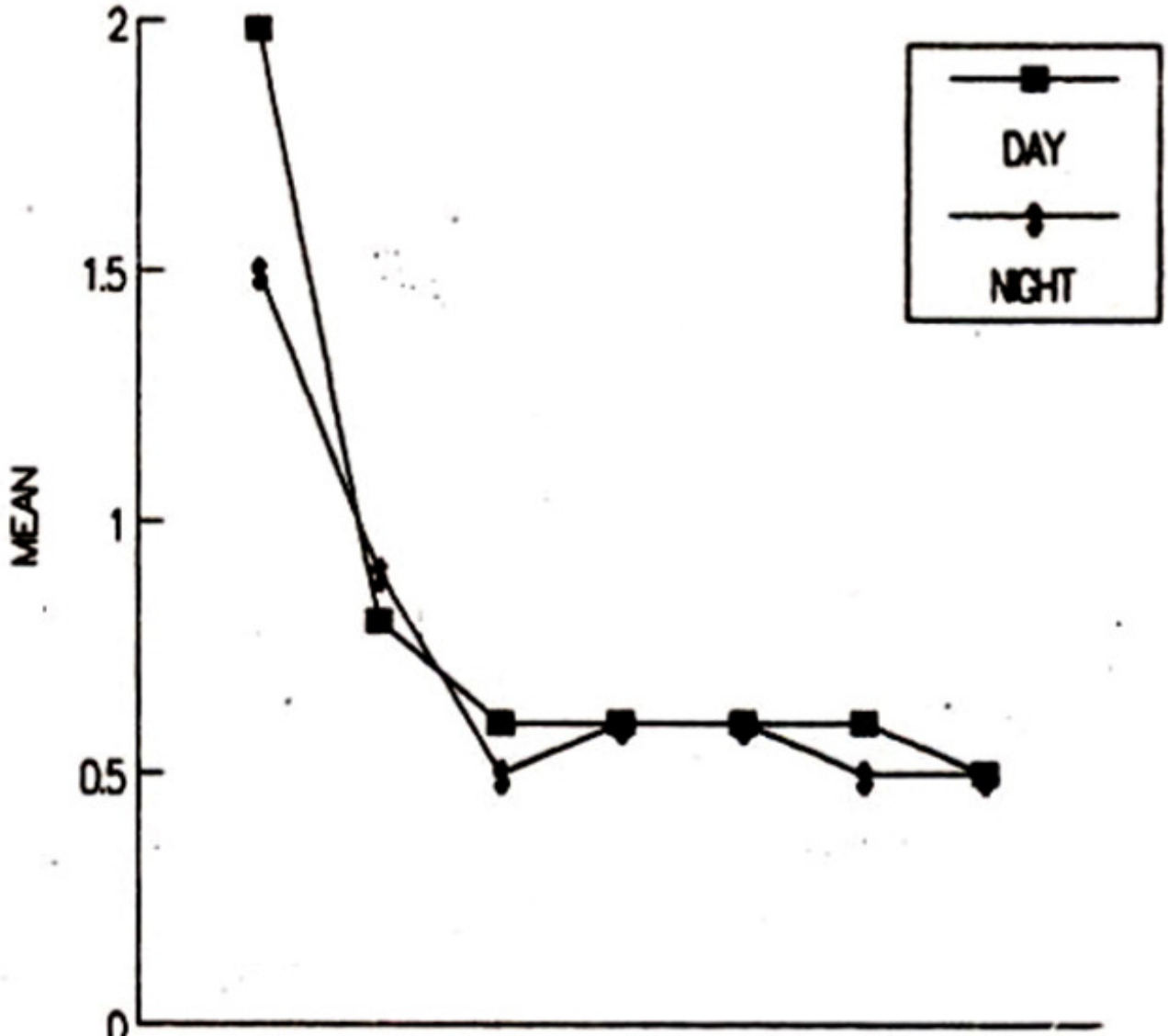

Figure. Heart burn scores.

and twelve cases (63%) became completely asymptomatic within six weeks of treatment. Apart from one patient who corn- plained of giddiness no other side effects were noted. No significant abnormalities in laboratory values were noted as compared to the initial readings and at the completion of trial.

Discussion

Present study revealed that the patients with reflux oesophagitis are predominantly males and are over forty years of age. Majority of them were tea drinkers, 32%were smokers, tobacco chewing and coffee intake was least common while alcohol intake was non- existent, which is different from west where alcohol consumption and smoking are the predominant addictions encountered[6]. This study provides a good evidence that famotidine 40 mg B.I.D. is quite effective in the treatment of moderate to severe reflux oesophagitis and majority of the cases (84%) healed with high dosage of famotidine within six

weeks. The healing rate inthis study is superior to that of ranitidine 300mg twice daily and is similartoprotonpumpinhibitorat 12 weeks reported earlier[7]. Previous studies have shown that in patients with symptomatic gastro-oesophageal reflux but no oesophagitis, both heartburn and Oesophageal mucosal sensitivity improve with famotidine 40 mg twice daily[8]. This dose was chosen because dose ranging studies have shown that it produces a greater reduction of oesophageal acid reflux than 20 mg twice daily or 40 mg at night and similarly it produces better symptomatic relief than other dosage regimen in patients with reflux oesophagitis[9]. Relief of symptoms especially the heartburn was very marked within first week of treatment, the score fell from the baseline of 2.0 to 0.8 for day time and 1.5 to 0.9 at night. This relief of symptom was maintained and further improved with subsequent dosage.

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