Abstract

Triple therapy was given to 49 chronic helicobacter pylori positive chronic duodenal ulcer cases to see its efficacy in H. pylori clearance, eradication and ulcer healing. H. pylori clearance and eradication rates at week 5 and 8 were 87.8% and 81.5% while ulcer healing rates 68.2% and 81.5% respectively. Seven (18%) cases failed to clear H. pylori and were classified as non-responders. Histologically 60% showed post-treatment regression of gastritis. Tolerance to drugs was excellent with a good compliance rate (JPMA 45: 2,1995).

Introduction

Since the introduction of helicobacter pylori as one of the major etiological factors in duodenal ulcer disease, lot of work has been done on the effect of its clearance and eradication on duodenal ulcer healing. Though the sensitivity of H. pylori to various bismuth compounds is well established but its eradication rates are low (20%)6-8. Mono-therapy with other antimicrobials also has a low eradication rate9. Dual therapy either with two antibiotics or an antibiotic with a bismuth salt improves eradication rates to 48-74%,1,8 while triple therapy (bismuth salt, metronidazole and another antibiotic) escalates these figures to 65-94%, with an almost 90% ulcer healing rate3,10,11. Metronidazole resistance, patient compliance and adverse effects are likely to alter the response12,14. In the present study, efficacy of triple therapy in clearance and eradication of H. pylori and duodenal ulcer healing was evaluated.

Patients and Methods

Forty-nine consecutive duodenal ulcer cases who had previously received various H2 receptor antagonists or proton pump inhibitors, presenting with a duodenal ulcer relapse were included in the study. All medications were stopped for 24 hours and a fresh endoscopy without sedation was done in all cases. At endoscopy apart from confirming a chronic ulcer, 3 antral biopsies were taken 5 cms around the pylonis. One biopsy was picked with a disposable needle and embedded in the CLO gel prepared locally15 while 2 others were placed in 10% buffered formalin for assessment of histologic gastritis and H. pylori colonization16. Only those cases were given triple therapy whose CLO test turned positive within 15 minutes of embedding.

Triple therapy consisted of tab colloidal bismuth subcitrate (De- Nol) x QID for 4 weeks, metronidazole (400 mg) TDS and amoxicillin (500 mg) TDS for 15 days. Endoscopy was repeated at weeks i and 8 and on both occasions 2 antral biopsies were taken for CLO test and histology.

Histological gastritis and H. pylori colonization were defined using criteria described elsewhere15. Ulcer healing, compliance and side effects were noted at each of these 2 visits. H. pylori clearance and eradication were defined as negative CLO and histology at weeks 5 and 8 respectively17. Those who
failed to clear *H. pylori* at week 8 were defined as non-responders.

**Results**

A total of 49 endoscopically confirmed chronic duodenal ulcer cases were included in the study. There were 42 males and 7 females with a mean age of 37 years. All patients had a positive CLO test at the entry into the trial. Antral biopsy in majority (73%) showed chronic atrophic gastritis with activity and histological evidence of *H. pylori* colonization. At week 5, eight patients were lost to follow-up leaving 41 cases for analysis. *H. pylori* clearance rate was 87.8% (36/41). At week 8, three more patients were dropped from the trial [lost to follow-up (1), intractable pain (1) and pyloric stenosis (1)] leaving 38 patients for analysis. *H. pylori* eradication rate was 81.5%. Seven (18%) patients failed to clear *H. pylori* at week 8 and were therefore classified as non-responders. Ulcer healing rates were 68.2% and 81.5% at week 5 and 8 respectively. Histologically 60% patients showed improvement as seen by regression of atrophic gastritis with activity to superficial gastritis without activity. Only one patient developed ulceration of mouth, but was able to complete the trial as per protocol. All others tolerated the drugs well. Compliance was not a problem in this study; though majority complained of a delayed pain relief (7-10 days).

**Discussion**

Though a wide variety of tests are available for the diagnosis of *H. pylori* infection but CLO test is the most rapid and reliable method. Response to therapy using bismuth compounds for *H. pylori* is well established and side effects like neurotoxicity can be prevented by prescribing low dose for a short time. Using monotherapy the *H. pylori* clearance rate was 77% which rose to 88% following triple therapy in the present study, indicating a better response with a combination therapy. An eradication rate of 81% is similar to 89% reported by others. With high endemicity of *H. pylori* in our population, an eradication rate of 81% is very encouraging. The therapy was highly effective in duodenal ulcer healing with 81% ulcer healing at 8 weeks. Similar figures were reported with various H2 receptor antagonists. Ulcer healing was closely associated with *H. pylori* clearance in this study. Lack of *H. pylori* clearance in 18% cases may indicate a possible amoxicillin or metronidazole resistance due to indiscriminate use of these drugs in our population. As compliance and side effects are not a major problem in our setup, efforts should be made to identify yet another antibiotic for the treatment of *H. pylori* using culture and sensitivity techniques.

**Acknowledgement**

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**References**