Ten mg dexrabeprazole daily is as effective as 20 mg rabeprazole daily

Rajendra Kanakia, Suresh Jain

Abstract
Ten mg dexrabeprazole daily has been shown to be more effective than 20 mg rabeprazole daily against gastroesophageal reflux disease (GERD). This report shows that the efficacy of 10 mg dexrabeprazole daily is equivalent to that of 20 mg dexrabeprazole daily against GERD. This implies that a dose of 10 mg dexrabeprazole is sufficient to block the maximum amount of proton pumps without any need to double the dose as suggested with rabeprazole.

© 2008 The WJG Press. All rights reserved.

Key words: Dexrabeprazole; Rabeprazole; Gastroesophageal reflux disease

TO THE EDITOR
We read with interest the article by Pai et al on the efficacy of 10 mg dexrabeprazole[1]. However, the effects of rabeprazole on acid secretion are dose-dependent, and an increase in gastric pH, coupled with a reduction in oesophageal acid exposure, has been seen in gastro-esophageal reflux disease (GERD) patients receiving 20 mg or 40 mg rabeprazole once daily[2]. Shimatani et al[3] showed that 20 mg rabeprazole, twice daily, may result in better acid suppression than 10 mg rabeprazole, twice daily, in GERD patients[3]. Hence, we wanted to find out whether 20 mg dexrabeprazole daily would provide a greater efficacy than 10 mg dexrabeprazole daily against GERD.

This was a randomized, double-blinded, comparative study in clinical setting, approved by the institutional review board and conducted in accordance with the Declaration of Helsinki and Good Clinical Practice guidelines. Males and non-pregnant and non-lactating females between the age of 18-65 years, clinically diagnosed with GERD, were included after a written informed consent was obtained from each of them. Excluded from the study were those with abnormal laboratory tests at baseline (including liver enzymes greater than twice the upper limit of normal), those who were refractory to a 2-mo course of H2-blocker or PPI therapy for GERD treatment, those who took PPI within 14 d of screening or a H2-blocker or a prokinetic agent within 7 d of screening, those who required daily use of NSAIDs, oral steroids, aspirin or were unable to discontinue the use of anticholinergics, cholinergics, spasmolytics, opiates or sucralfate, and those with poorly controlled associated disease, such as heart disease, coagulation disorders, thyroid disorders. Patients having a history of infectious or inflammatory conditions of the intestine (including inflammatory bowel disease), malabsorption syndrome, obstruction, gastrointestinal malignancy, gastric or intestinal surgery including vagotomy, Barrett's esophagus, esophageal stricture, pyloric stenosis, scleroderma or a history of hypersensitivity to any of the PPIs, were also excluded from the study. Enrolled patients were randomized to receive 10 mg dexrabeprazole once daily (D10-OD), 10 mg dexrabeprazole twice daily (D10-BD) or 20 mg dexrabeprazole daily (D20-OD) for 28 d. Visual analog scale (VAS, 0-100) was used to assess the severity of GERD symptoms. A total of 136 patients were enrolled and all completed the study. No difference was found in the baseline demographics of the patients.

A significant reduction (P < 0.001, Tukey-Kramer multiple comparison test) from baseline (day 0, before therapy) VAS scores of heartburn and regurgitation was
seen in all the treatment groups on day 14 with a further reduction on continuing the therapy until 28 d. Improvement in the VAS scores in the D10-OD group was significantly better than in the D10-BD and D20-OD groups on day 14 with no significant difference between the D10-BD and D20-OD groups. On day 28, the D10-OD group showed significantly higher improvement than the D10-BD group with no significant differences between the D10-OD & D20-OD and the D10-BD & D20-OD groups (Table 1). Percentage of patients with ≥50% relief in symptoms of heartburn and regurgitation on day 28 was 86.5% and 91.9% in the D10-OD group, 91.2% and 97.1% in the D10-BD group, 89.3% and 92.9% in the D20-OD group, respectively. No between-group difference in proportion of patients with ≥50% relief was observed (P > 0.05, chi-square test). None of the patients reported any adverse drug reaction and no differences were seen in baseline laboratory parameters after therapy, indicating that dexrabeprazole at different doses was well-tolerated.

The results of this study demonstrates that the efficacy of 10 mg dexrabeprazole daily is equivalent to that of 20 mg dexrabeprazole daily in relieving symptoms of GERD. This implies that 10 mg dexrabeprazole daily is potent and sufficient enough to block the maximum amount of proton pumps, thus precluding the need to use higher doses as has been suggested with rabeprazole.

REFERENCES

1 Pai V, Pai N. Randomized, double-blind, comparative study of dexrabeprazole 10 mg versus rabeprazole 20 mg in the treatment of gastroesophageal reflux disease. World J Gastroenterol 2007; 13: 4100-4102

2 Langtry HD, Markham A. Rabeprazole: a review of its use in acid-related gastrointestinal disorders. Drugs 1999; 58: 725-742

3 Shimatani T, Moriwaki M, Xu J, Tazuma S, Inoue M. Acid-suppressive effects of rabeprazole: comparing 10mg and 20mg twice daily in Japanese Helicobacter pylori-negative and -positive CYP2C19 extensive metabolisers. Dig Liver Dis 2006; 38: 802-808

---

Table 1 Improvement in Visual Analog Scale (VAS) scores of symptoms (values expressed as mean ± SD)

|                      | Day 0                          | Day 14                         | Day 28                         |
|----------------------|-------------------------------|-------------------------------|-------------------------------|
|                      | D10-OD (A, n = 74)            | D10-OD (A, n = 74)            | D10-OD (A, n = 74)            |
| Heartburn            | 48.5 ± 22.2                   | 59.7 ± 12.4                   | 58.2 ± 13.6                   |
| Between group        | 0.007<sup>a</sup>             | 0.007<sup>a</sup>             | 0.033<sup>b</sup>             |
| P values             | 0.001<sup>a</sup>             | 0.001<sup>a</sup>             | 0.012<sup>b</sup>             |
| Regurgitation        | 45.9 ± 20.4                   | 57.6 ± 12.6                   | 56.4 ± 14.5                  |
| Between group        | 0.003<sup>a</sup>             | 0.003<sup>a</sup>             | 0.014<sup>a</sup>             |
| P values             | 0.001<sup>a</sup>             | 0.001<sup>a</sup>             | 0.001<sup>a</sup>             |

<sup>a</sup> P < 0.001 vs baseline values (Tukey-Kramer Multiple comparison test). Between-group difference (T-test): 'A vs B; 'A vs C; 'B vs C.