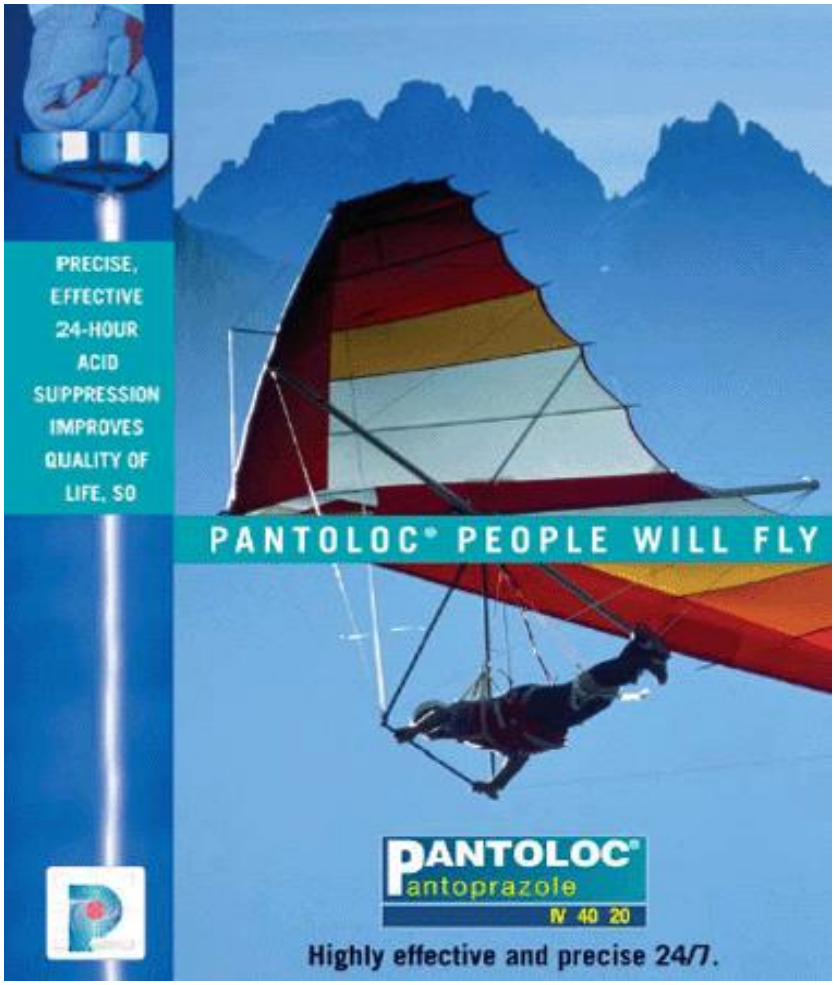
Medical Chronicle

Pantoprazole Rapidly Improves Health-related Quality of Life in Patients With Heartburn

Gastroesophageal reflux disease (GERD) is a frequently occurring condition with 7% to 10% of the population experiencing heartburn weekly. GERD has routinely been identified using biological markers such as erosions. However, erosions are often not present in patients with heartburn and up to 50% of patients have GERD without macroscopic oesophagitis. Documentation of oesophagitis, as a biological marker, is usually not available to the primary-care clinician, and recent guidelines for GERD management recommend an empirical approach with a therapeutic trial of antisecretory agents for patients with no alarm symptoms. Impairment of health-related quality of life (HRQoL) has been proposed as an important element of the definition of GERD. Therefore, tools to assess how symptoms of GERD relate to and impair patientsâ€™ HRQoL are important for a better understanding of diagnosis and treatment. Indeed, adequate control of symptoms of GERD has been defined as a sustained reduction of symptoms to a level that does not significantly impair HRQoL. Furthermore, the speed of the change in HRQoL during therapy may influence the choice of the treatment drug. In a prospective, randomised, double-blind comparative study, after seven days of treatment, HRQoL scores in all scales improved to a greater degree in pantoprazole-treated patients than in nizatidine-treated patients. In comparison to baseline, 2 SF-36 domains (bodily pain and vitality) and the GSRS reflux score showed a statistically significant difference between the two treatment groups. After 28 days of treatment, the changes in scores remained statistically significant in favour of pantoprazole.

Rapid improvememnt of symptoms and HRQol This study was conducted in a mixed population of symptomatic patients who had been confirmed to have either erosive oesophagitis (EE) or endoscopy-negative reflux disease, in proportion similar to those encountered in primary-care clinical practice. The respective current guidelines of the American College of Gastroenterology, as well as the Canadian Consensus, and an international workshop on management of GERD, recommend initial treatment of patients with heartburn without endoscopy when alarm symptoms are not present. Proton pump inhibitors (PPIs) have demonstrated superiority over histamine H 2 -receptor antagonists (H 2 -RAs) in healing erosive oesophagitis, for relieving symptoms in patients with oesophagitis, and with endoscopy-negative reflux disease (ENRD). Since assessment of symptoms is subjective, an additional outcome measure such as changes in HRQoL during drug therapy helps support the clinical superiority of pantoprazole in acute treatment of heartburn patients. In the present study, improvement of HRQoL occurred as early as seven days after treatment with pantoprazole or nizatidine. However, improvements achieved with pantoprazole



were significantly greater. After seven days of treatment, pantoprazole produced complete heartburn relief in 40% of the patients; this was approximately three times more frequently than in those treated with nizatidine. It is known that during the first seven days of therapy, pantoprazole can decrease acid secretion much more profoundly than the H 2 -RA, ranitidine. Results of this study confirm the value of pantoprazole as a possible diagnostic tool in the assessment of GERD since pantoprazole rapidly improves both symptoms and HRQoL of GERD patients with heartburn. The HRQoL results using pantoprazole showed complete relief of heartburn after 28 days produced in 63% of patients. This is consistent with the early development of pharmacological tolerance to H 2 -RAs and with the sustained and profound acid inhibition achieved by pantoprazole. On the first day of a 28-day period of therapy, pantoprazole is as potent as the maximal inhibitory efficacy of ranitidine on intragastric acidity.

Statistically significant benefits

In this study, HRQoL improved to a significantly greater extent in EE than in ENRD patients. While both drugs resulted in a comparable HRQoL improvement in ENRD patients, pantoprazole produced greater improvement in EE patients. Similar results were observed for symptom relief. Complete heartburn relief was seen in 70% of the pantoprazoletreated group and in 34% of the nizatidine group in EE patients. In another large comparative trial of GERD patients with grade 0 and mild EE, pantoprazole 20mg od achieved statistically significant therapeutic gain in complete relief of heartburn in comparison to ranitidine 150mg bid (88% versus 69%, $p<0.001$). In summary, for GERD patients treated on the basis of their heartburn without the use of endoscopy, HRQoL improves more rapidly and to a greater extent after treatment with pantoprazole 40mg od than after treatment with nizatidine 150mg bid. The superiority of pantoprazole was sustained during the first 28 days of therapy. It appears that during acute treatment of GERD, for patients who exhibit heartburn as their main symptom, without any alarm features, the degree of symptom control is strongly predictive of improvement in their HRQoL. Thus, at the primarycare level, these results favour the use of a PPI, such as pantoprazole, for the initial treatment of heartburn and reflux symptoms, rather than an H 2 -RA.

ParÃ© P, Armstrong D et al. Pantoprazole rapidly improves health-related quality of life in patients with heartburn: A prospective, randomized, double blind comparative study with nizatidine. J Clin Gastroenterol 2003;37(2):132-138. This information was sponsored by Altana Madaus (Pty) Ltd.