

Proton pump inhibitor pantoprazole provides rapid relief from reflux, largest-ever Canadian gastro study finds

Toronto, ON – July 29, 2002 Symptoms of gastroesophageal reflux (GERD) improve significantly within days after treatment with the proton-pump inhibitor (PPI) pantoprazole has been initiated, and almost one-third of patients are completely free of symptoms by day 7.

Those are among the results of the largest gastro study ever undertaken in Canada. The study, called the Patient Evaluation Program (PEP), permitted Canadian physicians to enroll patients whose upper gastrointestinal tract (GI) symptoms were likely to respond to PPI therapy. Once identified, treatment with pantoprazole 40 mg a day was initiated, leading to rapid symptomatic relief in most patients whose symptoms were most likely to be caused by GERD.

The study found that the proportion of patients who reported severe or very severe symptoms of GERD dropped from 53% at onset to 14% by the end of the seventh day of treatment with pantoprazole.

PEP involved 2,273 patients from across Canada and 726 Canadian physicians, including 601 family physicians, 39 surgeons, 22 internists and 64 gastroenterologists. Physicians recorded their patients' diagnosis based on the most suggestive symptoms. (Patients could have more than one diagnosis). Slightly over 78% of survey participants were diagnosed as having GERD, while slightly over 13% were judged to have either a duodenal or gastric ulcer.

Over 20% were felt to have something other than GERD or an ulcer. (A firm diagnosis of either GERD or ulcer can only be made on diagnostic endoscopy, which is not readily available for primary care physicians.)

After diagnosis, patients were given a month's supply of pantoprazole to be taken once daily. Prior to initiating treatment, patients were required to assess the presence and severity of eight GI-related symptoms in a daily symptom diary.

Once treatment had been initiated, participants tracked symptomatic response to treatment in their daily diaries over the ensuing month. Analyses revealed that the proportion of patients who became symptom-free during the first seven days of treatment ranged from 44% for the symptom of burping, to 73% for nocturnal reflux. Symptom severity also fell progressively and significantly from baseline to day 7.

A significant reduction in severity of acid regurgitation was also observed, at a mean severity score of 1.35 at day 7 compared with 2.21 at baseline. Similar magnitudes of reduction in symptom severity scores were also documented for bloating, nausea, slow digestion and burping. Not surprisingly, the fall in severity scores for symptoms of GERD was most marked in patients diagnosed with GERD by their physicians.

"Ideally, treatment should be based on a firm diagnosis," said Dr. David Armstrong, the lead investigator and an assistant professor, department of medicine at McMaster University in Hamilton, Ontario. However, upper GI symptoms are extremely common, affecting up to 30% of the adult population. Waiting for consultation with a specialist and diagnostic endoscopy can also take as long as six months, and in the meantime, primary care physicians need an effective therapy to provide relief for patients with suspected GERD or ulcer.

"Proton pump inhibitor therapy is a plausible short-term, initial strategy for many common upper GI tract symptoms and a reasonable long-term strategy for those with an established diagnosis of acid-peptic disease," Dr. Armstrong said. "In a predominantly primary care population, such as that observed in this survey, therapy with a proton pump inhibitor such as pantoprazole is likely to produce a good symptomatic response for patients with upper gastrointestinal symptoms."

Pantoprazole (Pantoloc) is among Canada's fastest growing prescription products and is co-marketed in Canada by Markham-based Solvay Pharma Inc. and Oakville-based Byk Canada Inc.

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