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Effects on 24-Hour Intragastric pH: A Comparison of Lansoprazole Administered Nasogastrically in Apple Juice and Pantoprazole Administered Intravenously

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OBJECTIVE: To compare the 24-h intragastric pH effects of lansoprazole, 30 mg administered nasogastrically, with pantoprazole, 40 mg administered *i.v.*

METHODS: Healthy adults were enrolled in an open label, two-way crossover, single-center study. Thirty milligrams of lansoprazole (administered nasogastrically in apple juice) or pantoprazole (*i.v.*) were administered once daily at 8:00 AM for 5 consecutive days with at least a 2-wk washout period between the regimens. Ambulatory 24-h intragastric pH was monitored at baseline and on days 1 and 5 of each treatment period. Blood specimens were collected on days 1 and 5 for pharmacokinetic parameter determinations.

RESULTS: Thirty-three adults completed both crossover periods, with the exception of one patient with a zero lansoprazole plasma concentration on day 1 of period 2. Lansoprazole, 30 mg per nasogastric tube, produced significantly higher mean 24-h intragastric pH values relative to pantoprazole, 40 mg *i.v.*, on both day 1 (3.05 *vs* 2.76, $p < 0.002$) and day 5 (3.65 *vs* 3.45, $p = 0.024$). Lansoprazole sustained the intragastric pH above 3 (days 1 and 5), 4, and 5 (day 1) significantly longer relative to pantoprazole. Lansoprazole's time to the maximum observed concentration and area under the plasma concentration–time curve over the 24-h time interval increased significantly from day 1 to day 5 (1.7 h *vs* 2.0 h and 1865 ng · h/ml *vs* 2091 ng · h/ml, respectively), and a significant increase in half-life relative to day 1 (0.96 h) was observed on day 5 (1.03 h) during pantoprazole treatment.

CONCLUSION: Lansoprazole, 30 mg administered nasogastrically, effectively controls intragastric pH and is an alternative to *i.v.* pantoprazole in patients who are unable to swallow solid dosage formulations. (Am J Gastroenterol 2001;96:2058–2065. © 2001 by Am. Coll. of Gastroenterology)

INTRODUCTION

It is well established that proton pump inhibitors (PPIs) effectively suppress gastric acid secretion and are superior to histamine-2 receptor antagonists in this regard. Effective control of intragastric pH is directly related to healing of duodenal and gastric ulcers, erosive esophagitis healing, and the relief of reflux-related symptoms (1–4). Jones and colleagues (1) found a highly significant predictable relationship between the healing of ulcers and the degree and duration of intragastric acid suppression and the length of treatment. Effective suppression of intragastric pH is also correlated with a decrease in the recurrence of esophageal mucosal injury (4).

There are several clinical situations where gastric acid inhibitory therapy is needed but patients are unable to swallow solid oral dosage formulations. In these individuals, effective alternatives to *i.v.* administration of therapeutic agents are clinically desirable. Lansoprazole, a PPI, has high bioavailability after *p.o.* administration—80–90% after the first dose and stable thereafter (5–12). Several studies have confirmed that the lansoprazole capsules can be opened and the intact granules sprinkled on applesauce or prepared as various liquid formulations without compromising its bioavailability or acid suppressant efficacy (13–18). Effective control of the intragastric pH was also noted in studies where the intact granules were mixed with apple juice (40 ml) and injected through a nasogastric tube into the stomach, followed by flushing the nasogastric tube with additional apple juice to clear the tubing (14).

Pantoprazole, another PPI, has been studied as a 40-mg enteric-coated tablet and as a solution for *i.v.* administration. Administered as an *i.v.* infusion, pantoprazole produces a rapid (onset of <1 h) dose dependent suppression of acid output (19). The oral formulation of pantoprazole has a high (approximately 80%) bioavailability, with the effects on gastric acid secretion being comparable after equal doses of the *p.o.* enteric tablet or *i.v.* formulation (20–22).