

● G0587

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## ● G0590

**OMEPRAZOLE OR RANITIDINE BISMUTH CITRATE WITH CLARITHROMYCIN AND AMOXICILLIN FOR 10 DAYS TO TREAT *H. PYLORI* INFECTION: A RANDOMIZED, CONTROLLED TRIAL IN VIETNAMESE PATIENTS WITH DUODENAL ULCER.**

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The effectiveness of different *H. pylori* (*Hp*) therapies has not been consistent in different parts of the world. Potential explanations for these differences include varied protocols, bacterial factors, and/or host factors. In Vietnam, *Hp* infection is endemic and clinical diseases associated with this infection including peptic ulcer and gastric adenocarcinoma are common. We report the first randomized, controlled study from Vietnam to evaluate the effectiveness of proton pump inhibitor or ranitidine bismuth citrate (RBC)-based triple therapy. Patients with *Hp* infection and duodenal ulcer (DU) were enrolled from Tran-Hung Dao Hospital (Hanoi, VN). A DU was defined as a mucosal lesion of > 5 mm with depth. *Hp* was documented during the index EGD with rapid urease testing (RUT, Pyloritek, Serim Research) and histology (H&E with Giemsa in selected cases). Histology was performed by an experienced GI pathologist in Vietnam. Infected patients were randomized in double-blind fashion to either omeprazole 20mg (OAC) or RBC 400mg (RAC) with amoxicillin 1gm and clarithromycin 500mg BID for 10 days. 4-6 weeks after therapy, patients underwent a second EGD to assess ulcer healing and obtain biopsies for RUT and histology. Compliance and side effects were documented by a diary completed by the patient and an interview at mid-treatment and again within a week of completing therapy. The goal of our study was to enroll 50 patients in each group. Per protocol (PP) and intention to treat (ITT) eradication rates and ulcer healing rates were calculated. From 10/97 to 8/98, 108 Vietnamese natives (34 females, mean age 45yrs (17-75yrs)) were found to have a DU. 104/108 (96%) DU patients were infected with *Hp* by either RUT or histology and randomized to OAC (57) or RAC (47). 99/104 (54 OAC and 45 RAC) returned for the second endoscopy. In the OAC group, 5/6 patients with a DU at the second EGD had persistent *Hp*. The sole RAC patient with a persistent DU had no *Hp* by RUT or histology. There was 100% compliance to both regimens. Side effects were mild with equal incidence in both groups. The most commonly reported side effects were heartburn (7.4%) and loose stools (3.1%). No patient withdrew because of side effects. **Conclusions:** 1. Unlike the USA, DU is nearly always associated with *Hp* in Vietnam. 2. Both OAC and RAC for 10 days yielded excellent rates of *Hp* eradication in Vietnamese patients with DU. 3. Ulcer healing occurred in those successfully cured of *Hp* and did not require additional acid suppression beyond the 10 day treatment period.

	Hp Eradication		Ulcer Healing	
	PP	ITT	PP	ITT
OAC	48/54 (89%)	48/57 (84%)	48/54 (89%)	48/57 (84%)
RAC	43/45 (96%)	43/47 (91%)	43/45 (96%)	44/47 (94%)