

Efficacies of Genotypic Resistance-Guided vs Empirical Therapy for Refractory *Helicobacter pylori* Infection

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		Eradication rate	
		Trial 1* (N=41)	Trial 2* (N=410)
Patients with refractory <i>H. pylori</i> randomized	Genotypic resistance guided therapy	81% (17/21)	78% (160/205)
	Empirical therapy	60% (12/20)	72.2% (148/205)
		vs	vs
		p=0.181	p=0.170
*Independent trials. Doxycycline and tetracycline were used as part of the study drugs in trial 1 and trial 2, respectively.			Gastroenterology

BACKGROUND & AIMS: We aimed to compare the efficacy of genotypic resistance-guided therapy vs empirical therapy for eradication of refractory *Helicobacter pylori* infection in randomized controlled trials. **METHODS:** We performed 2 multicenter, open-label trials of patients with *H pylori* infection (20 years or older) failed by 2 or more previous treatment regimens, from October 2012 through September 2017 in Taiwan. The patients were randomly assigned to groups given genotypic resistance-guided therapy for 14 days (n = 21 in trial 1, n = 205 in trial 2) or empirical therapy according to medication history for 14 days (n = 20 in trial 1, n = 205 in trial 2). Patients received sequential therapy containing esomeprazole and amoxicillin for the first 7 days, followed by esomeprazole and metronidazole, with levofloxacin, clarithromycin, or tetracycline (doxycycline in trial 1, tetracycline in trial 2) for another 7 days (all given twice daily) based on genotype markers of

resistance determined from gastric biopsy specimens (group A) or empirical therapy according to medication history. Resistance-associated mutations in 23S ribosomal RNA or gyrase A were identified by polymerase chain reaction with direct sequencing. Eradication status was determined by ¹³C-urea breath test. The primary outcome was eradication rate. **RESULTS:** *H pylori* infection was eradicated in 17 of 21 (81%) patients receiving genotype resistance-guided therapy and 12 of 20 (60%) patients receiving empirical therapy (P = .181) in trial 1. This trial was terminated ahead of schedule due to the low rate of eradication in patients given doxycycline sequential therapy (15 of 26 [57.7%]). In trial 2, *H pylori* infection was eradicated in 160 of 205 (78%) patients receiving genotype resistance-guided therapy and 148 of 205 (72.2%) patients receiving empirical therapy (P = .170), according to intent to treat analysis. The frequencies of adverse effects and

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