Modified 7-day versus Standard 10-day Concomitant Therapy for *Helicobacter Pylori* Eradication in Thai Patients: A Randomized Controlled Trial

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**Background:** Eradication rates for *Helicobacter pylori* with a standard triple therapy have declined in Thailand and globally. A 10-day standard concomitant therapy (SCT) is another first-line *H. pylori* treatment option with slightly higher eradication rates. However, SCT is associated with more side effects when compared to a triple therapy. In particular, more aggressive acid suppression may allow shortening treatment duration without compromising eradication rates.

**Objectives:** This study aimed to compare the *H. pylori* eradication rates between a 7-day modified concomitant therapy (MCT) and a 10-day SCT.

**Materials and Methods:** This open label, randomized study was conducted at Rajvithi Hospital, Bangkok, Thailand during November 2016 – November 2017. Patients with active *H. pylori* infection (n=240) were included and randomized (1:1) into either 7-day MCT (omeprazole 40 mg b.i.d., amoxicillin 1000 mg b.i.d., clarithromycin 500 mg b.i.d. and metronidazole 400 mg t.i.d. for 7 days) or 10-day SCT (omeprazole 20 mg b.i.d., amoxicillin 1000 mg b.i.d., clarithromycin 500 mg b.i.d. and metronidazole 400 mg t.i.d. for 10 days). *H. pylori* eradication was evaluated by 14C-urea breath test at 4-6 weeks after the completion of treatment. Eradication rates were analyzed by per-protocol (PP) and intention-to-treat (ITT) analysis. Side effects and patient compliance were recorded.

**Results:** A total of 120 patients were randomized into each treatment group. In the ITT analysis, *H. pylori* eradication rates were 88.3% (106/120) and 88.3% (106/120) in the 7-day MCT and the 10-day SCT groups, respectively (p>0.99). In the PP analysis, *H. pylori* eradication rates were 94.6% (106/112) and 95.5% (106/111) in the 7-day MCT and 10-day SCT groups, respectively (p=0.769). Bitter taste was the most commonly reported side effect in both groups (72.3% in the 7-day MCT vs 66.7% in the 10-day SCT, p=0.36). Headache (9.8% vs 18.9%, p=0.05) and diarrhea (17% vs 27.9%, p=0.05) were less commonly reported in the 7-day MCT group than the 10-day SCT group, respectively.

**Conclusions:** The 7-day MCT was safe with similar achievable eradication rates compared to the 10-day SCT. Due to its better tolerability, the 7-day MCT may be a practical alternative first-line treatment option for *H. pylori* eradication in Thailand.

**Keywords:** Concomitant therapy, *Helicobacter pylori*, Thailand