中文題目：比較以混合療法及高劑量二合一療法作為幽門螺旋桿菌第一線治療之效益:一前瞻性隨機研究。

英文題目：**Comparison between Hybrid Therapy and High Dose Dual Therapy for First-line *Helicobacter Pylori* Eradication: A Prospective Randomized Controlled Trial**

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Background: The application of hybrid therapy can achieve a high success rate for *Helicobacter pylori* (*H. pylori*) eradication, even in patients who are resistant to clarithromycin. On the other hand, high dose dual therapy (HDDT) is able to lengthen the duration of high intra-gastric pH and was reported to achieve a high eradication rate too. This randomized controlled study compares the real world success rate of naive *H.pylori* eradication between hybrid therapy and HDDT and to investigate the factors that affect the eradication rates.

Methods: We recruited 163 eligible *H. pylori*-infected patients after exclusion. They were randomly assigned to 14 days of hybrid therapy (RACM-14, rabeprazole 20 mg and amoxicillin 1 g b.i.d. for 7 days, followed by rabeprazole 20 mg, amoxicillin 1 g, clarithromycin 500 mg, and metronidazole 500 mg b.i.d. for 7 days) or a 14 days of HDDT (RA-14, rabeprazole 20 mg and amoxicillin 750 mg q.i.d for 14 days). Three patients were lost during follow-up (2 in RACM-14 and 1 in RA-14 group, resulting in 80 for RACM-14 group and 80 for RA-14 group in the per protocol (PP) study. The participants were asked to performed urea breath tests eight weeks later.

Results: The eradication rates for RACM-14 and RA-14 groups were 92.7% (95% confidence interval [CI] = 84.8%-97.3%) and 85.2% (95% CI = 75.6%-92.1%) (p=0.127) in intention-to-treat analysis; 95.0% (95% CI: 87.7%–98.6%) and 86.3% [95% CI: 72.8%–93.0%] (p = 0.058) in per protocol analysis. The adverse event rates were 8.8% in the RA-14 group and 16.5% in the RACM-14 group (p = 0.143). Samples from 79 patients were cultured for *H. pylori,* and the positive culture rate was 92.4% (73/79). Hence, the antibiotic resistance rates were amoxicillin (1.3%), clarithromycin (10.1%), metronidazole (40.5%), and dual resistance to clarithromycin and

metronidazole (5.1%).

Conclusions: Hybrid therapy attained > 90% of successful eradication rate, compared to > 85% in HDDT for first line *H.pylori* eradication.

Keywords：*Helicobacter pylori* infection, hybrid therapy, high dose dual therapy, antibiotic susceptibility