中文題目：以 Dexlansoprazole MR 為基礎不含鉍劑四合一幽門螺旋桿菌第一線治療之效益: 一前瞻性研究

英文題目：The Efficacy of Dexlansoprazole MR-based Non-bismuth Quadruple Therapy for First Line *Helicobacter pylori* Eradication: A Prospective Randomized Trial

作　　者：余冠璋[1], 戴維震[1,2], 梁志明[1], 胡琮輝[1,2], 蔡成枝[1,2]

服務單位：[1]高雄長庚醫院內科部, [2]高雄長庚醫院內科部胃腸肝膽系

Background*:* Non-Bismuth containing quadruple therapy (Concomitant therapy) can achieve a promising success rate of >90-% in the presence of clarithromycin resistance. High dose PPI is needed with a dosage of twice daily but when a dual delayed release formulation PPI in capsules for oral administration (Dexlansoprazole MR), a once daily dose may be need only. The capsules contain dexlansoprazole in a mixture of two types of enteric-coated granules with different pH-dependent dissolution profiles. We performed a prospective, randomized controlled study to assess the efficacy of Dexlansoprazole MR-based Concomitant therapy and investigate the influencing clinical factors.

Method*:* We recruited 202 out of 248 eligible *H. pylori*-infected patients after exclusion. They were randomly assigned to 7-day Dexlansoprazole MR-based Concomitant therapy (Dexlansoprazole MR 60 mg once daily, clarithromycin 500 mg twice daily, amoxicillin 1 g twice daily. and metronidazole 500 mg twice daily for 7 days, DACM group) or a 7-day lansoprazole-based Concomitant (Lansoprazole 30 mg twice daily, clarithromycin 500 mg twice daily, amoxicillin 1 g twice daily and metronidazole 500 mg twice daily for 7 days, LACM group). Urea breath tests were followed-up 8 weeks later.

Results:A total of 246 eligible *H. pylori*-infected patients endoscopically proven peptic ulcer diseases or gastritis were invited 202 patients were enrolled (n=101 per group) in the Intention-to-treat (ITT) analysis. Ultimately, 5 patients were lost during follow-up in DACM group; 3 patients in LACM group, resulting in 96 for DACM group and 98 in the PP study for LACM group. The eradication rates of the DACM and LACM groups. ITT analysis demonstrates similar eradication rates in the two study groups 86.1% (95% CI= 77.8%-92.2%) and 90.1 % (95% CI = 82.6%-95.2%) (P=0.384). According to the Per-protocol (PP) analysis, the success rates of eradication *H. pylori* infection were DACM 90.6% (95% CI= 82.9%-95.6%) and LACM 92.6% (95% CI= 85.5%-96.9%) (P=0.572).

The adverse event rates were 11.5% in DACM group and 10.2% in LACM group, p=0.779. These adverse events included abdominal pain, diarrhea, dizziness, headache, and nausea/vomiting; however, these were mild and did not markedly disturb the patients' daily activities. Therefore, both groups had good drug compliances (100%). Univariate analysis showed that antibiotics resistance to clarithromycin, metronidazole and dual resistance to both clarithromycin and metronidazole were the clinical factor influencing the efficacy of *H. pylori* eradication therapy (P=0.043, p=0.003, and p<0.001respectively).

Samples from 42 patients were cultured for *H. pylori*, and the positive culture rate was 90.5% (38/42). Hence, the antibiotic resistance rates were amoxicillin (0%), clarithromycin (21%) and metronidazole (26.32%). The *H. pylori* eradication rates for the amoxicillin and clarithromycin susceptible strains were 100% (14/14) (95% CI: 76.8 %-100.0 %) in DACM, and 93.8% (15/16), (95% CI: 69.8 %-99.9%) in LACM.

Conclusions:Dexlansoprazole MR-based Concomitant therapy achieves a high PP eradication rate for the first-line anti-*H.Pylori* therapy comparable to 7-day Lansoprazole-based Concomitant therapy.

ClinicalTrials.gov number: NCT03383003