

中文題目：比較含鉍劑四合一療法、非鉍劑四合一療法與 14 天的標準三合一療法在幽門桿菌第一線療效之比較：一項多中心隨機分派臨床試驗

英文題目：Concomitant, bismuth quadruple, and 14-day triple therapy in the first-line treatment of *Helicobacter pylori* - a multicentre randomized trial

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前言(Background): Whether concomitant therapy is superior to bismuth quadruple therapy or 14-day triple therapy in the first line treatment of *Helicobacter pylori* (*H. pylori*) infection remains poorly understood. We aimed to compare the efficacy and safety of 10-day concomitant therapy, 10-day bismuth quadruple therapy, and 14-day triple therapy in the first-line treatment of *H. pylori*.

材料及方法(Materials and Methods): For this multicentre, open-label, randomised trial, we recruited adult patients (≥ 20 years of age) with *H. pylori* infection from 9 centres in Taiwan. Using a computer-generated randomisation sequence, we randomly allocated patients (1:1:1; block sizes of six) to either concomitant therapy (lansoprazole 30mg, amoxicillin 1gm, clarithromycin 500mg, and metronidazole 500mg, all given twice daily) for 10 days or bismuth quadruple therapy (bismuth tripotassium dicitrate 300 mg four times a day, lansoprazole 30mg twice daily, tetracycline 500mg four times a day, and metronidazole 500mg three times a day) for 10 days or triple therapy (lansoprazole 30mg, amoxicillin 1gm, and clarithromycin 500mg, all given twice daily) for 14 days. Our primary outcome was the eradication rate in the first-line therapy by intention-to-treat (ITT) analysis. Investigators were masked to treatment allocation. This trial is registered with ClinicalTrials.gov, number NCT01906879.

結果(Results): The eradication rates of 10-day bismuth quadruple therapy, 10-day concomitant therapy, and 14-day triple therapy were 90.4% (488/540, 95% CI 87.6%-92.6%), 85.9% (464/540, 95% CI 82.7%-88.6%), and 83.7% (452/540, 95% CI 80.4%-86.6%) in the ITT analysis, respectively. 10-day bismuth quadruple therapy was superior to 14-day triple therapy (difference 6.7%, 95% confidence interval (CI) 2.7%-10.7%, $p=0.001$). 10-day concomitant therapy was not superior to 14-day triple therapy. 10-day bismuth quadruple therapy was not superior to 10-day concomitant therapy. The frequencies of adverse effects in patients treated with 10-day bismuth quadruple therapy, 10-day concomitant therapy, and 14-day triple therapy

were 67.2% (358/533, 95% CI 63%-71.1%), 57.8% (309/535, 95% CI 53.4%-62%), and 47.1% (252/535, 95% CI 42.8%-51.4%), respectively ($p < 0.001$).

結論(Conclusion): Bismuth quadruple therapy is preferable to 14-day triple therapy in the first-line treatment in the face of rising prevalence of clarithromycin resistance. Concomitant therapy given for 10 days might not be optimal and a longer treatment length should be considered.

Keywords: *Helicobacter pylori*, bismuth quadruple, concomitant therapy, 14-day triple therapy

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海報題目：比較含鈹劑四合一療法、非鈹劑四合一療法與 14 天的標準三合一療法
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