

中文題目:比較含 levofloxacin 序列療法與含鉍劑四合一療法在幽門螺旋桿菌第二線及第三線除菌治療之療效-一項多中心隨機分派臨床試驗

英文題目: Levofloxacin sequential therapy versus bismuth quadruple therapy in the second-line and third-line treatment of *Helicobacter pylori* -a multicenter randomized trial

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前言 (Background): We aimed to compare the efficacy and safety of 14-day levofloxacin sequential therapy versus 10-day bismuth quadruple therapy in the second-line and third-line treatment of *Helicobacter pylori* (*H. pylori*) infection

材料及方法 (Materials and Methods): *H. pylori* infected patients who failed after one treatment were eligible in this open labeled, multicenter, randomized trial, and were randomized to receive (1) levofloxacin sequential therapy (EAML): esomeprazole 40 mg and amoxicillin 1 g for the first 7 days, followed by esomeprazole 40 mg, metronidazole 500 mg, and levofloxacin 250 mg for another 7 days (all twice daily); or (2) bismuth quadruple therapy (BQ): esomeprazole 40mg twice daily, bismuth tripotassium dicitrate 300 mg four times a day, tetracycline 500mg four times a day, and metronidazole 500mg three times a day, for 10 days. The primary end point was the eradication rate in the second-line treatment according to intention to treat (ITT) analysis. The minimum inhibitory concentrations were determined by agar dilution test.

結果 (Results): A total of 560 patients have been recruited. The demographic characteristics and antibiotic resistance rates were similar across the two treatment groups. The eradication rate in the second line treatment were 86.2% (238/276) and 87.4% (242/277) in the levofloxacin sequential therapy and bismuth quadruple therapy groups, respectively (p=0.694) in the ITT analysis. The eradication rates were 87.8% (238/271) and 92% (242/263) in the levofloxacin sequential therapy and bismuth quadruple therapy according to PP analyses, respectively (p=0.108). The efficacy of levofloxacin sequential therapy, but not bismuth quadruple therapy, appeared to be affected by levofloxacin resistance. The frequency of any adverse effects was higher in patients treated with bismuth quadruple therapy than levofloxacin sequential therapy (76.4% vs. 44.1%, p<0.001). The efficacy of bismuth quadruple therapy and levofloxacin sequential therapy in the third-line treatment were 70.6% (12/17) and 63.6%(7/11), respectively.

結論 (Conclusion): Levofloxacin sequential therapy and bismuth quadruple therapy are similarly effective in the second-line treatment for *H. pylori* infection. (Trial registration number: NCT NCT03148366)

Keywords: refractory *H. pylori*, resistance, levofloxacin, bismuth quadruple