

中文題目：含levofloxacin的序列性治療與含levofloxacin的三合一治療在幽門桿菌第二線療效之比較:一項多中心隨機分派臨床試驗

英文題目：Levofloxacin sequential therapy versus levofloxacin triple therapy in the second line treatment of *Helicobacter pylori*: A multicenter randomized trial

作者：劉志銘¹ 白明忠² 陳介章¹ 李宜家¹ 張吉仰³ 方佑仁⁴ 陳柏岳⁵ 吳政毅⁶
張君照⁷ 林肇堂^{1,8} 吳明賢¹

服務單位：台大醫學院附設醫院內科¹ 台東馬偕醫院內科² 義大醫院內科³ 台大醫學院附設醫院雲林分院內科⁴ 嘉義基督教醫院內科⁵ 高雄醫學院附設醫院及大同醫院內科⁶ 台北醫學院附設醫院內科⁷ 輔大醫學院內科⁸

前言(Background): The efficacy of levofloxacin triple therapy has fallen below 80% in the second line treatment of *Helicobacter pylori* (*H. pylori*). We aimed to assess whether the levofloxacin sequential therapy is more effective than levofloxacin triple therapy in the second line treatment.

材料及方法(Materials and Methods): This open-label, randomized, multicenter trial was conducted between 2012 and 2015. *H. pylori* infected subjects who failed from clarithromycin-based regimens (N=600) were randomized (1:1) to receive levofloxacin sequential therapy (LS: lansoprazole and amoxicillin for the first 5 days, followed by lansoprazole, levofloxacin, and metronidazole for another 5 days) or levofloxacin triple therapy (LT: lansoprazole, amoxicillin, and levofloxacin for 10 days). Successful eradication was defined as negative ¹³C-urea breath test at least 6 weeks after treatment. Our primary outcome was the eradication rate by intention-to-treat (ITT) and per-protocol (PP) analyses. Antibiotic resistance was determined by agar dilution test..

結果(Results): The prevalence of clarithromycin, levofloxacin, and metronidazole resistance were 60%, 17.6%, and 36.9%, respectively. The eradication rates of LS and LT were 84.3% (253/300) and 75.3% (226/300), respectively, in the ITT analysis ($p=0.006$) and were 86.3% (253/293) and 78.8% (223/283), respectively, in the PP analysis ($p=0.021$). The efficacy of LS and LT were both affected by levofloxacin resistance. The secondary resistance of levofloxacin was 66.7% and 73.9% after LS and LT, respectively. The efficacy of LS and LT were not affected by the CYP2C19 polymorphism.

結論(Conclusion): Levofloxacin sequential therapy was more effective than levofloxacin triple therapy and is recommended in the second line treatment for *H. pylori*. ClinicalTrials.gov number: NCT01537055

Keywords: *Helicobacter pylori*, second line, levofloxacin, resistance, sequential, triple