

中文題目：比較依抗藥性基因與依用藥史引導療法在幽門螺旋桿菌第三線以上治療之療效
英文題目：Comparison of genotypic resistance guided therapy versus medication history guided therapy in the third-line treatment of refractory *H. pylori* infection

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前言 (Background): Whereas the Maastricht IV and V Consensus recommended the use of susceptibility testing guided therapy for patients with refractory *H. pylori* infection, the Toronto Consensus recommended the use of empirical therapy according to medication history. Our previous pilot trial showed that genotypic resistance guided therapy was effective (eradication rate 82%) in the third-line rescue therapy. Therefore, we aimed to compare the efficacy of genotypic resistance guided versus empirical selection of antibiotics in the third line treatment for refractory *H. pylori* infection.

材料及方法 (Materials and Methods): This multicenter, open label, parallel group, randomized trial was conducted since 2013.01.01. Adult (≥ 20 years old) patients who failed from at least two eradication therapies for *H. pylori* infection were enrolled. Genotypic and phenotypic resistances of clarithromycin (23S rRNA) and levofloxacin (gyrase A) were determined by PCR with direct sequencing. Eligible patients will be randomized into either one of the treatment groups (A) genotypic resistance guided sequential therapy for 14 days; or (B) medication history guided sequential therapy for 14 days. Eradication status will be determined by ¹³C-urea breath test. The primary outcome was the eradication rate in the third line treatment (genotypic versus empiric) according to intention-to-treat (ITT) analysis.

結果 (Results): A total of 451 patients have been randomized. The demographic characteristics, including the prevalence of antibiotic resistance before third-line treatment, were similar

among the two treatment groups. The eradication rates in patients treated with genotypic resistance guided therapy and empirical therapy were 78.4% (178/227) and 71.4% (160/224) in the ITT analysis, respectively ($p=0.087$), and were 79% (178/224) and 73.4% (157/214) in the PP analysis, respectively ($p=0.165$). The frequency of any adverse effects were not significantly different between the two groups (50.4% vs. 50.7%, $p=0.961$). The compliance (taking at least 80% of the study drugs) were similar between the two groups (99% vs. 98.4%, $p=0.622$).

結論 (Conclusion): This is the first randomized trial to show that empirical therapy according to medication therapy may achieve similar efficacy to that of genotypic resistance guided therapy in the third-line treatment of refractory infection and may be an alternative strategy when susceptibility testing is not available.

Keywords: refractory *H. pylori*, resistance, genotypic, medication history, sequential therapy