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Is concomitant quadruple therapy for *Helicobacter pylori* eradication really needed for Japanese patients?

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Abstract

The study found that the 7 d of concomitant therapy (lansoprazole, amoxicillin, clarithromycin and metronidazole) achieved significantly higher eradication rates compared to 7 d of triple therapy (lansoprazole, amoxicillin, clarithromycin), the intention to treat (ITT) cure rates being 94.9% and 68.3%, respectively. According to our opinion, this study is clinically relevant for Japanese physicians for at least 2 reasons: (1) the standard triple therapy (clarithromycin plus amoxicillin) achieved disappointing cure rates in Japan - in agreement with what was observed in several countries; and (2) the concomitant quadruple therapy is an effective therapeutic alternative.

Key words: *Helicobacter pylori*; Triple therapy; Japanese patients

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TO THE EDITOR

We read with great interest the study by Yanai *et al*[1] which compared the efficacy of a non-bismuth, concomitant, quadruple therapy and that of a standard triple therapy. In detail, the study found that the 7 d of concomitant therapy (lansoprazole, amoxicillin, clarithromycin and metronidazole) achieved significantly higher eradication rates compared to 7 d of triple therapy (lansoprazole, amoxicillin, clarithromycin), the intention to treat (ITT) cure rates being 94.9% and 68.3%, respectively. According to our opinion, this study is clinically relevant for Japanese physicians for at least 2 reasons: (1) the standard triple therapy (clarithromycin plus amoxicillin) achieved disappointing cure rates in Japan - in agreement to what was observed in several countries[2,3]; and (2) the concomitant quadruple therapy is an effective therapeutic alternative. The authors commented that the high success rate achieved following the concomitant therapy is most likely due to the addition of metronidazole to the standard clarithromycin-amoxicillin-based triple therapy. Indeed, they claimed that the primary *Helicobacter pylori* (*H. pylori*) metronidazole resistance rate (4.5%) in Japan is distinctly lower than the 50%-70% observed in other Asian countries. This would appear to be a convincing explanation. However, it has also been claimed that in their previous experience, "*H. pylori* infection was cured in 91%, 91.2% and 86.5% of atrophic gastritis, gastric ulcer and duodenal ulcer patients by ITT analyses (unpublished data)" by using a 7 d triple therapy with lansoprazole 30 mg, amoxicillin 750 mg and metronidazole 200 mg twice daily. Therefore, the authors would claim that the success

rate of a metronidazole-based triple therapy (about 90%) is significantly lower than that of a metronidazole-based quadruple therapy (about 95%)[1]. Besides that a direct comparison between 2 different studies is unreliable, we calculated that the 95% confidence intervals of the eradication rate (49/52; 94.9%) achieved with the concomitant therapy are 87.9%-100%. Such an eradication range clearly overlaps with the cure rates achieved with the simpler metronidazole-amoxicillin triple therapy they experienced. Therefore, the reasons for the authors choosing a triple therapy of amoxicillin with clarithromycin rather than with metronidazole as a control therapy are not clear. Indeed, for ethical concerns, it has been suggested that new therapy for *H. pylori* eradication should be compared with the most effective available therapy[4,5]. Most likely, there would be no statistically significant difference between the concomitant therapy and the metronidazole-amoxicillin triple therapy[1]. Therefore, the use of a quadruple, concomitant therapy instead of a simpler metronidazole-based triple therapy in Japan would not appear to be justified.

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