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LETTERS TO THE EDITOR

Furazolidone therapy for *Helicobacter pylori*: Is it effective and safe?

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Abstract

Some aspects related with the use of furazolidone as a rescue therapy for *Helicobacter pylori* (*H pylori*) infection should be remarked, especially regarding its potential oncologic risk. The inclusion of furazolidone in a treatment regimen for *H pylori* infection is, at least, controversial, and it does not appear to be safe.

Key words: *Helicobacter pylori*; Therapy; Furazolidone; Rescue therapy

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TO THE EDITOR

We have read with great interest the study performed in Brazil by Felga *et al*[1] on the efficacy and safety of a 'rescue' therapy to cure *Helicobacter pylori (H pylori)* infection. Briefly, following a quadruple therapy including PPI, bismuth salts, amoxicillin and furazolidone, a 68.8% eradication rate was achieved, a side-effect incidence of 31.4% was observed, and treatment interruption occurred in 3 (6.7%) out of 45 controlled patients. The authors concluded that 'it is an effective, cheap and safe option for salvage therapy'. We have some concerns about these conclusions. First, in the manuscript, the eradication rate was calculated only at 'per protocol' analysis (68.8%; 31 of 45). However, by calculating the success rate at 'intention to treat' analysis (all the 51 treated patients), the eradication rate was as low as 60.8%. Therefore, this quadruple therapy would not appear so 'effective' as declared. Indeed, it has been found that a simpler, levofloxacin-amoxicillin triple therapy achieved a higher eradication rate as a second-line therapy or even 'rescue' therapy[2,3]. The reported side-effect incidence (31.4%) was much higher than that observed following furazolidone-free therapies, which was lower than 10% with an interruption rate as low as 0.003%-0.007% in thousands of patients[4]. This observation suggests that treatment with furazolidone is not so 'safe' as declared. Last but not the least, some crucial ethical concerns arise with the use of furazolidone. This is an antibiotic used in the 1980s for parasitic infections and some studies described its use in human subjects to treat *H pylori* infection. However, different studies were published that raised several concerns about this agent and its potential for causing tumors[5,6]. Moreover, the company that made the agent in the United States (Roberts Pharmaceuticals) was sold to Shire Pharmaceuticals and the FDA withdrew its approval for furazolidone in March 2005. The drug was ordered to be removed even from animals as an antibiotic by the FDA in 2002. The FDA has subsequently sued companies that illegally imported the drug from Mexico for use in animals. Simultaneously, the European Medicinal Agency (EMEA; the equivalent of the FDA in the European Union) banned the drug in Europe. Although the drug continues to be available in some developing countries such as Iran, Pakistan, India, Mexico and Brazil, a number of public and press campaigns from concerned individuals have urged governments to ban the drug in those countries. Therefore, can we consider a therapy including furazolidone to be 'safe' as the authors declared? Although it has been stated that study was approved by the Ethical Committee, were patients informed of possible genotoxic and carcinogenetic effects for which furazolidone is not currently approved by both FDA and EMEA?

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