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ORIGINAL ARTICLE

Eradication of *Helicobacter pylori* infection with a new bismuth-based quadruple therapy in clinical practice[☆]

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KEYWORDS

Helicobacter pylori;
Bismuth-based
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Pylera[®];
Eradication;
Probiotics

Abstract

Introduction: The eradication of *Helicobacter pylori* infection represents a clinical challenge. **Objective:** To evaluate the efficacy and safety of quadruple therapy with esomeprazole plus a 3-in-1 capsule containing bismuth subcitrate, metronidazole and tetracycline, plus probiotics in patients diagnosed with *H. pylori* infection in routine clinical practice.

Methods: A prospective, interventional, single-centre and open-label study in consecutive patients with a confirmed indication for eradication of *H. pylori* infection. Patients were treated with three capsules of Pylera[®] four times a day (breakfast, lunch, afternoon snack and dinner), plus 40 mg of esomeprazole twice daily for 10 days (30 min before breakfast and dinner) and probiotics for 30 days. Eradication of *H. pylori* infection was confirmed by labelled urea breath test performed at least 28 days after the end of treatment.

Results: A total of 100 patients were consecutively enrolled. Twenty-five patients (25.0%) had a prior history of treatment for their *H. pylori* infection. In the intention-to-treat population, eradication rates were 90.7% (68/75) and 80.0% (20/25) in patients treated with Pylera[®] as the first line or as rescue therapy, respectively. Eighteen patients (18%) had at least one adverse event, most of which (89%) were mild.

Conclusion: Ten days of treatment with a quadruple regimen of bismuth, metronidazole and tetracycline plus esomeprazole and probiotics is an effective and safe strategy in patients with *H. pylori* infection.

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PALABRAS CLAVE

Helicobacter pylori;
Terapia cuádruple
basada en bismuto;
Pylera[®];
Erradicación;
Probióticos

Erradicación de la infección por *Helicobacter pylori* con una nueva terapia cuádruple basada en bismuto en la práctica clínica

Resumen

Introducción: La erradicación de la infección por *Helicobacter pylori* representa un desafío clínico.

Objetivo: Evaluar la eficacia y seguridad de la terapia cuádruple con esomeprazol más una cápsula 3 en 1 que contiene subcitrate de bismuto, metronidazol y tetraciclina, más probióticos en pacientes diagnosticados de infección por *H. pylori* en la práctica clínica habitual.

Métodos: Estudio prospectivo, intervencional, unicéntrico y abierto realizado en pacientes consecutivos con indicación confirmada de erradicación de infección por *H. pylori*. Los pacientes fueron tratados con 3 cápsulas de Pylera[®] 4 veces al día (desayuno, comida, merienda y cena), más 40 mg de esomeprazol, 2 veces al día durante 10 días (30 min antes de desayuno y cena) y probióticos durante 30 días. La erradicación de la infección por *H. pylori* se confirmó mediante la prueba del aliento con urea marcada realizada al menos 28 días después del final del tratamiento.

Resultados: Un total de 100 pacientes fueron incluidos consecutivamente. Veinticinco (25,0%) pacientes tenían historia previa de tratamiento de su infección por *H. pylori*. En la población por intención de tratar, las tasas de erradicación fueron del 90,7% (68/75) y del 80,0% (20/25) en los pacientes tratados con Pylera[®] como primera línea o como terapia de rescate, respectivamente. Dieciocho pacientes (18%) presentaron, al menos, un acontecimiento adverso, la mayoría (89%) leves.

Conclusión: Diez días de tratamiento con un régimen cuádruple de bismuto, metronidazol y tetraciclina más esomeprazol y probióticos es una estrategia eficaz y segura en pacientes con infección por *H. pylori*.

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Introduction

Helicobacter pylori is one of the most prevalent pathogens in humans, affecting more than 50% of the population.^{1,2}

H. pylori infection causes chronic inflammation of the gastric mucosa and is responsible for a significant number of gastrointestinal diseases, such as duodenal or gastric ulcers (in 1–10% of infected patients), gastric cancer (in 0.1–3%) and gastric mucosa-associated lymphoid tissue (MALT) lymphoma (in 0.01%).^{3–6}

The treatment of choice to eradicate *H. pylori* infection was initially a triple-therapy regimen comprising a proton pump inhibitor (PPI) plus 2 of the following 3 antibiotics: clarithromycin, amoxicillin or metronidazole. However, over recent years, its efficacy has fallen to unacceptable levels in many countries, mostly due to increasing levels of bacterial resistance.^{7–10}

According to recommendations of the IV Spanish Consensus Conference on treatment for *H. pylori* infection, an effective treatment should be able to eradicate *H. pylori* infection in approximately 90% of patients.¹¹

A triple-therapy regimen with omeprazole, amoxicillin and clarithromycin (OAC) is unsuitable when local rates of clarithromycin resistance exceed 15%.^{11,12} In Spain, mean resistance rates of 18.3% for clarithromycin, 40.8% for metronidazole and 10.1% for both have been published.¹³ Furthermore, one recently published study identified resistance rates to clarithromycin of 33% in children.¹⁴

The drop in *H. pylori* infection eradication rate has led to the development of new therapeutic strategies.^{15–17}

In Spain, the first-line therapy that is currently recommended is a concomitant, non-bismuth, quadruple therapy regimen (PPI, clarithromycin, amoxicillin and metronidazole).¹¹

Recommendations of the IV Spanish Consensus Conference on treatment for *H. pylori* infection indicate that, after failure of a triple or quadruple therapy including clarithromycin, preferably a levofloxacin-containing quadruple therapy (PPI, amoxicillin, levofloxacin and bismuth) or, alternatively, a bismuth-containing quadruple therapy (PPI, bismuth, tetracycline and metronidazole) is recommended.¹¹

It is possible to use doxycycline instead of tetracycline, although experience with its use is much more limited, and there are doubts regarding its therapeutic equivalence.¹¹

Recommendations of the Maastricht V/Florence Consensus Report¹² indicate that a quadruple-therapy regimen comprising bismuth, metronidazole and tetracycline (BMT) plus omeprazole (PPI) obtains a high eradication rate in patients in whom other therapeutic alternatives had previously failed.

According to scientific evidence available to date, BMT-PPI therapies achieve high eradication rates when administered as first-line therapy^{18–23} and when administered as rescue therapy.^{24–29} One of the advantages of BMT-PPI therapy is that no *H. pylori* resistance to bismuth

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