Current regimens for treatment of 
*Helicobacter pylori* infection

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The aim of treatment of *Helicobacter pylori* is eradication of the bacterium from the foregut. Treatment is difficult because of the bacterium’s habitat and acquired resistance to commonly used antibiotics. Dual therapy, the 2 week combination of omeprazole or ranitidine bismuth citrate and either amoxycillin or clarithromycin, eradicates *H. pylori* in 50–80% of patients. Classical triple therapy is commonly associated with side effects, is highly dependent on patient’s compliance, and is significantly less effective in the presence of metronidazole-resistant strains of *H. pylori*, where eradication may be 50%. One week, twice daily, proton pump inhibitor (PPI)-based triple therapy regimens eradicate about 90% of *H. pylori* and are associated with mild side effects. Second line regimens include 7 days treatment with omeprazole and 3 times daily amoxycillin and metronidazole or a PPI-based quadruple therapy regimen. In some cases, the bacterium defeats all attempts at eradication.

The aim of treatment of *H. pylori* infection in any clinical situation is eradication of the bacterium from the foregut. Eradication is currently defined as negative tests for *H. pylori* at least 28 days after the end of antimicrobial therapy.

Treatment of *H. pylori* infection is difficult for two main reasons. First, the bacterium lives below the gastric mucus adherent to the gastric epithelium and access of antimicrobial drugs to this site is restricted, both from the lumen of the stomach and from the gastric blood supply.

Second, *H. pylori* may have acquired resistance to the commonly used antimicrobial agents, such as 5-nitroimidazoles (metronidazole, tinidazole) and macrolides (clarithromycin). Pre-treatment metronidazole-resistant strains (MRS) of *H. pylori* are more common among ethnic minorities where these drugs may have been used previously to treat infectious diarrhoea. In such cases, the prevalence of MRS of *H. pylori* may be as high as 95%\(^1\). Pretreatment clarithromycin-resistant strains (CRS) of *H. pylori* are less common, but are increasing in prevalence because of widespread use of this drug in the community to treat respiratory tract infections\(^2-3\). In the UK, less than 5% of *H. pylori* have acquired resistance.
Helicobacter infection to clarithromycin, but, in Spain and France, the prevalence of CRS of *H. pylori* may be as high as 15%\(^2,3\). As a result of acquired resistance to the commonly used agents, treatment regimens have been developed using two or more antimicrobial drugs, for example triple or quadruple therapy regimens. Although these are effective, somewhat complex treatment schedules and unwanted effects of the drugs, may lessen compliance and thus their efficacy\(^4\).

The ideal therapy for *H. pylori* eradication should be simple, safe, free from side effects, with 100% efficacy and low cost. The ideal treatment regimen has not yet been defined. Research in this area has been complicated by the small number of randomised, controlled trials and the large number of studies mainly published as abstracts (70%, 576 of 823 publications to date). Moreover, details of doses and duration of treatment vary between the various trials, limiting the scope for meta-analysis.

Current eradication regimens are discussed under the heading of dual, classic triple, low-dose triple and quadruple therapy, depending on the number and dose of antimicrobial agents used concurrently in the treatment. Eradication percentage is reported using an intent-to-treat (‘worst-case’) analysis whereby all patients treated are included in the analysis even if they failed to take the drugs or return for follow-up; in which case they are assumed to be treatment failures. Intent-to-treat analysis provides a more realistic assessment of the *H. pylori* eradication therapy than a per-protocol analysis (‘best-case’) whereby only those patients taking the majority (or all) of the drugs and returning for follow-up are included. A per-protocol analysis provides data about the efficacy of a particular regimen under ideal circumstances, but the results may not be reproducible outside of clinical trials.

**Dual therapy**

Dual therapy refers to the combination of omeprazole or ranitidine bismuth citrate (RBC) and either amoxycillin or clarithromycin. These regimens were reported to overcome problems that had bedevilled classic triple therapy, such as side effects, MRS of *H. pylori* and patient's compliance with more complex regimens.

**Omeprazole and amoxycillin**

Most of the work dealing with dual therapy uses omeprazole and amoxycillin (Table 1), is published as abstracts and is based on small,
uncontrolled, non-randomised studies. The results suggest that the daily dose of amoxycillin should be at least 2 g; the frequency of administration appears to be less important than the compliance with the treatment regimen. In combination with amoxycillin, omeprazole is more effective when given twice daily and at higher than normal doses. Thus, eradication with omeprazole 20 mg or 40 mg once daily with amoxycillin 2 g daily for 2 weeks varies between 0% and 28%, but on 20–40 mg twice daily in combination with amoxycillin 1 g twice daily (or 500 mg, 4 times daily) for 2 weeks, eradication was 50–90%. However, recent data from large, double-blind, randomised controlled trials of 2 weeks’ treatment with omeprazole (20 or 40 mg twice daily) and amoxycillin (500 mg or 1 g 3 times daily) reported *H. pylori* eradication of only 39–46%. There are less data on lansoprazole or pantoprazole, in combination with amoxycillin, but preliminary studies suggest that the results with these newer PPIs are similar.

**Omeprazole with clarithromycin**

Inhibition of acid secretion with PPIs increases the intragastric pH to 5.0 or more and significantly decreases the minimum inhibitory concentration (MIC) of amoxycillin and clarithromycin making them more effective. The combination of various dosages and duration of omeprazole, lansoprazole or pantoprazole with clarithromycin for *H. pylori* eradication have been studied (Table 2). The frequency of dosing with clarithromycin is important. Thus, clarithromycin 500 mg given twice daily in combination with omeprazole 40 mg was apparently less effective, with eradication reported as 56%, compared with 63–81% on clarithromycin 500 mg, 3 times daily. Side effects occur in up to half of patients treated with clarithromycin and omeprazole and become more common as the dose and frequency of clarithromycin increase, the commonest being taste disturbance. Clarithromycin is a relatively expensive antimicrobial agent, and a 2 week combination of omeprazole

<table>
<thead>
<tr>
<th>Table 1 Dual therapy with amoxycillin</th>
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<tbody>
<tr>
<td><strong>Dosing</strong></td>
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<tr>
<td>Omeprazole</td>
</tr>
<tr>
<td>Amoxycillin 20-40 mg twice daily</td>
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<tr>
<td>750 mg 3 times daily or 1g twice daily</td>
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</table>

Omeprazole with clarithromycin

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Table 2 Dual therapy with clarithromycin

<table>
<thead>
<tr>
<th></th>
<th>Omeprazole Clarithromycin</th>
<th>Ranitidine bismuth citrate Clarithromycin</th>
</tr>
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<tbody>
<tr>
<td>Dosing</td>
<td>40 mg once daily 500 mg 3 times daily</td>
<td>400 mg twice daily 500 mg twice daily</td>
</tr>
<tr>
<td>Duration</td>
<td>2 weeks</td>
<td></td>
</tr>
<tr>
<td>H. pylori eradication</td>
<td>80%</td>
<td></td>
</tr>
<tr>
<td>Side effects</td>
<td>Common: taste disturbances, diarrhoea</td>
<td></td>
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40 mg daily and clarithromycin 500 mg 3 times daily costs about £100, which is considerably more than most other regimens.

Ranitidine bismuth citrate

Ranitidine bismuth citrate (RBC) is a new chemical compound that combines the antisecretory activity of ranitidine with mucoprotective and H. pylori suppressive effects of bismuth. Dual therapy with RBC (400 mg twice daily) and amoxycillin (500 mg 4 times daily) or clarithromycin (250 mg 4 times daily or 500 mg twice daily) for 2 weeks is licensed for H. pylori eradication. RBC with amoxycillin will eradicate H. pylori in about 65% of cases\(^{13}\), but with clarithromycin 500 mg twice daily, the figures become about 80% (Tables 1 & 2)\(^ {14-16}\). Unfortunately, any possible advantages of twice daily dual therapy with RBC and clarithromycin are outweighed by the need for 14 days’ treatment and high treatment cost.

Classic triple therapy

Classic triple therapy (Table 3) consists of a bismuth compound (colloidal bismuth subcitrate (CBS) or bismuth subsalicylate, BSS), metronidazole and either amoxycillin or tetracycline. There are wide variations in the dosage and treatment schedules used in these regimens, with eradication results varying from 30–95\%\(^{6}\). It is difficult to account for these differences, except by invoking the customary factors of dissimilarities in patient populations, incidence of metronidazole resistance, degree of compliance with the treatment and the like. Triple therapy given for less than 7 days has not been successful and when given for longer than 14 days appears to give no further therapeutic advantage\(^ {6}\).

Classic triple therapy is significantly less effective against pretreatment MRS of H. pylori, with most eradication results falling between 30% and 60% in this group of patients\(^ {6,17,18}\).
Table 3  Triple therapy combinations with amoxicillin and metronidazole

<table>
<thead>
<tr>
<th>Omeprazole</th>
<th>Ranitidine</th>
<th>Colloidal bismuth subcitrate</th>
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</thead>
<tbody>
<tr>
<td>Amoxicillin</td>
<td>Amoxicillin</td>
<td>Tetracycline or amoxicillin</td>
</tr>
<tr>
<td>Metronidazole</td>
<td>Metronidazole</td>
<td>Metronidazole</td>
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</tbody>
</table>

<table>
<thead>
<tr>
<th>Dosing</th>
<th>Duration</th>
<th>H. pylori eradication</th>
<th>Side effects</th>
</tr>
</thead>
<tbody>
<tr>
<td>Omeprazole</td>
<td>Ranitidine</td>
<td>Colloidal bismuth subcitrate</td>
<td>Common: diarrhoea, nausea</td>
</tr>
<tr>
<td>Metronidazole</td>
<td>Ranitidine</td>
<td>Tetracycline or amoxicillin</td>
<td>Metronidazole</td>
</tr>
<tr>
<td>Amoxicillin</td>
<td>Ranitidine</td>
<td>Tetracycline or amoxicillin</td>
<td>Metronidazole</td>
</tr>
</tbody>
</table>

MSS = metronidazole-sensitive strains of *H. pylori*
MRS = metronidazole-resistant strains of *H. pylori*.

**Alternative triple therapy regimens**

Antisecretory drugs have been tried in place of bismuth as part of a triple therapy with some success (Table 3). Thus, ranitidine 300 mg daily combined with metronidazole 500 mg 3 times daily and amoxicillin 750 mg 3 times daily for 12 days was shown to eradicate around 90% of *H. pylori*\(^{19}\). However, this regimen is far less effective against MRS of *H. pylori*, where eradication is around 50%\(^{19,20}\).

The combination of omeprazole 40 mg\(^{21}\), lansoprazole 30 mg\(^{22}\) or pantoprazole 40 mg\(^{23}\) with amoxicillin 500 mg 3 times daily and metronidazole 400 mg 3 times daily for 1 week is an effective triple therapy, with *H. pylori* eradication in around 90% of the patients. In patients with pretreatment MRS of *H. pylori*, the omeprazole-based regimen was shown to be effective in about 75% of cases\(^{21}\). Thus, in areas with a high prevalence of MRS and CRS of *H. pylori*, 1 week's treatment with omeprazole, amoxicillin and metronidazole may be the first choice. Moreover, this regimen is one of the cheapest costing around £20.

**Low-dose triple therapy**

In 1993, Bazzoli and colleagues reported 100% *H. pylori* eradication in 36 patients using a 1 week, low-dose triple therapy regimen of omeprazole 20 mg daily, clarithromycin 250 mg and tinidazole 500 mg taken twice daily\(^{24}\). Subsequent studies in large randomised, comparative trials have confirmed that the combination of omeprazole\(^{25}\) or lansoprazole\(^{26}\) plus
Table 4 Low-dose triple therapy regimens

<table>
<thead>
<tr>
<th>Dosing</th>
<th>PPI</th>
<th>Clarithromycin</th>
<th>Metronidazole</th>
<th>PPI</th>
<th>Amoxycillin</th>
<th>Clarithromycin</th>
</tr>
</thead>
<tbody>
<tr>
<td>once daily or twice daily</td>
<td>once daily or twice daily</td>
<td>250 mg twice daily</td>
<td>400 mg twice daily</td>
<td>twice daily</td>
<td>1 g twice daily</td>
<td>250-500 mg twice daily</td>
</tr>
<tr>
<td>Duration</td>
<td>7 days</td>
<td>7 days</td>
<td>7 days</td>
<td>7 days</td>
<td>7 days</td>
<td>7 days</td>
</tr>
<tr>
<td>H. pylori eradication</td>
<td>90%</td>
<td>90%</td>
<td>90%</td>
<td>(75% in MRS)</td>
<td>(75% in MRS)</td>
<td>(75% in MRS)</td>
</tr>
</tbody>
</table>

PPI = proton pump inhibitor
MRS = metronidazole-resistant strains of *H. pylori*.

clarithromycin and a nitroimidazole or amoxycillin taken twice daily for 1 week will eradicate about 90% of *H. pylori* (Table 4). Similar results have been reported using pantoprazole. These low-dose regimens appear to be associated with few side-effects; nausea and diarrhoea being the commonest.

In combination with clarithromycin and a nitroimidazole, there appears to be no therapeutic advantage in increasing the dose of omeprazole above 20 mg daily, lansoprazole above 30 mg daily or pantoprazole above 40 mg daily. There is a paucity of data comparing the different PPIs using the same antimicrobials, but recently a randomised trial showed no significant difference in *H. pylori* eradication between lansoprazole 30 mg twice daily or omeprazole 20 mg twice daily in combination with amoxycillin 1 g twice daily and clarithromycin 500 mg twice daily.

The data are conflicting regarding the best dose of clarithromycin (250 or 500 mg twice daily) in combination with a PPI and either amoxycillin or metronidazole. In the MACH 1 study, omeprazole, amoxycillin and clarithromycin produced higher *H. pylori* eradication with clarithromycin 500 mg twice daily, but with omeprazole, metronidazole and clarithromycin, the lower dose of clarithromycin 250 mg twice daily was more effective. Interestingly, a study from Japan reported *H. pylori* eradication in 100 of 101 (99%) patients after 1 week's treatment with omeprazole 40 mg twice daily, amoxycillin 2 g twice daily and clarithromycin 1.6 g twice daily.

Preliminary data using twice daily RBC in combination with two antimicrobials look promising. A recently reported randomised study of RBC 400 mg twice daily, clarithromycin 500 mg twice daily and amoxycillin 1 g twice daily for 2 weeks reported *H. pylori* eradication in 21 of 22 (95%) patients (intent-to-treat). Similar results
were reported from a randomised study of 7 days' treatment with RBC 400 mg twice daily, clarithromycin 250 mg twice daily and metronidazole 500 mg twice daily with *H. pylori* eradication in 31 of 36 (86%) patients. Unfortunately, the prevalence of MRS of *H. pylori* was not determined. An open study of 1 week's treatment with RBC 400 mg twice daily, clarithromycin 500 mg twice daily and tetracycline 500 mg twice daily reported *H. pylori* eradication in 43 of 48 (90%) patients (intent-to-treat analysis). Side effects, such as diarrhoea, nausea and taste disturbances, were commonly reported.

**Effect of metronidazole-resistance**

In the UK and Eire multicentre study of 1 week, low-dose, PPI-based triple therapy regimens, pretreatment *H. pylori* antimicrobial sensitivities were determined on culture of gastric biopsies. The three metronidazole-containing regimens were similarly effective in patients with pretreatment MSS strains of *H. pylori*, but were significantly (*P < 0.05*) less effective against MRS of *H. pylori*. More recently, the efficacy of omeprazole, clarithromycin and metronidazole was reported to be significantly decreased against MRS of *H. pylori*, where *H. pylori* eradication decreased from 95% for strains susceptible to metronidazole to 76% for resistant strains. MRS of *H. pylori* may reach 90% prevalence in inner city areas, where the metronidazole-containing regimens may be less effective. In such areas, an eradication regimen comprising a PPI, amoxicillin and clarithromycin may be preferable.

**Duration of treatment**

Tompkins et al. recently reported the results of a randomised study using 5 days' treatment with lansoprazole 30 mg and clarithromycin 250 mg with either amoxicillin 1 g or metronidazole 400 mg; all drugs taken twice daily. Lansoprazole, amoxicillin and clarithromycin eradicated *H. pylori* in 29 of 47 (62%) patients, which is considerably less than that reported from a larger randomised trial using the same treatment for 7 days, where *H. pylori* was eradicated in 104 of 121 (86%) patients. Five days' treatment with lansoprazole, clarithromycin and metronidazole eradicated *H. pylori* in 38 of 45 (84%) patients. Interestingly, in those patients with MSS of *H. pylori* this 5 day treatment eradicated the bacterium in 13 of 14 patients (93%), but was significantly less effective in those with MRS of *H. pylori* (13 of 19, 68%). These findings suggest that, in the presence of MSS of *H. pylori*, 5 days' treatment with lansoprazole, clarithromycin and metronidazole
Table 5 Quadruple therapy

<table>
<thead>
<tr>
<th>PPI</th>
<th>Colloidal bismuth subcitrate</th>
</tr>
</thead>
<tbody>
<tr>
<td>Tetracycline</td>
<td></td>
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<tr>
<td>Metronidazole</td>
<td></td>
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<table>
<thead>
<tr>
<th>Dosing</th>
<th>once daily – twice daily</th>
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<tbody>
<tr>
<td></td>
<td>120 mg 4 times daily</td>
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<tr>
<td></td>
<td>500 mg 4 times daily</td>
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<tr>
<td></td>
<td>400-500 mg 4 times daily/3 times daily</td>
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<table>
<thead>
<tr>
<th>Duration</th>
<th>7 days</th>
</tr>
</thead>
<tbody>
<tr>
<td>H. pylori eradication</td>
<td>85–95%</td>
</tr>
</tbody>
</table>

Side effects: Common: diarrhoea, nausea

PPI = proton pump inhibitor.

may be enough, but if the antimicrobial resistance patterns of H. pylori are unknown, then at least 7 days’ treatment is required.

Is there any evidence to recommend using PPI-based triple therapy regimens for 10 days? The studies of 10 days’ treatment with omeprazole, amoxycillin and clarithromycin provide conflicting results\[41,42\]. A small randomised trial, compared 7, 10 or 14 days’ treatment with omeprazole 20 mg, amoxycillin 1 g and clarithromycin 500 mg twice daily and reported that H. pylori eradication was significantly (P < 0.05) higher (83%) with the 10 day, than with the 7 day (77%) regimen\[41\]. However, another study comparing 7 with 10 days’ treatment the same regimen reported 95% H. pylori eradication in both treatment arms\[43\].

Lerang et al\[33\], in a multicentre, randomised, double-blind study, reported H. pylori eradication in 72 of 76 (95%, intent-to-treat) patients treated for 10 days with twice daily omeprazole 20 mg, clarithromycin 250 mg and metronidazole 400 mg. The efficacy of this 10 day regimen was unaffected by the pretreatment metronidazole sensitivity of H. pylori, with eradication in 17 of 18 (94%) patients with MRS of H. pylori. These conflicting data on the importance of MRS of H. pylori when using PPI, clarithromycin and metronidazole cannot be resolved at present, but suggest that a 10 day treatment course of PPI, clarithromycin and metronidazole may overcome MRS of H. pylori.

Quadruple therapy

Quadruple therapy (Table 5) for H. pylori eradication must entail more compliance problems and side effects than the simpler regimens\[44,45\].
Despite this, 98% *H. pylori* eradication has been reported using a 1 week combination of omeprazole (20 mg twice daily given for 10 days), CBS (120 mg 4 times daily), tetracycline (500 mg 4 times daily) and metronidazole (500 mg 3 times daily). Compliance was remarkably high in this well performed study, and all patients were followed-up. Only 7.7% of the pretreatment *H. pylori* isolates were metronidazole resistant, and this may account for the very high eradication reported. Similar results have been reported using lansoprazole-based quadruple therapy regimens.

Twice daily quadruple therapy (bismuth subsalicylate, tetracycline 500 mg, metronidazole 500 mg and lansoprazole 15 mg) for 10 days was reported to be effective against MSS of *H. pylori* (95% eradication), but was significantly less effective against MRS of *H. pylori* (40% eradication) and is, therefore, of no benefit over simpler and shorter twice daily regimens.

**Conclusions**

At the time of writing this review article, the ideal treatment for *H. pylori* eradication does not exist. About 90% *H. pylori* eradication is possible after 1 week’s treatment with a PPI in combination with clarithromycin 250–500 mg and either amoxycillin 1 g or metronidazole 400 mg; all drugs taken twice daily. A second line regimen of 1 week’s treatment with omeprazole 40 mg daily, amoxycillin 500 mg 3 times daily and metronidazole 400 mg 3 times daily has been shown to eradicate *H. pylori* in over 75% of the first-line failures. Quadruple therapy is an alternate second line therapy in motivated patients, but otherwise is best reserved for third line. In some cases the bacterium defeats all attempts at eradication and definitive treatment may have to be abandoned; fortunately such instances are infrequent.

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