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Eradication of *Helicobacter pylori*: an objective assessment of current therapies

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The purpose of the present review was to determine objectively the optimal treatment for the eradication of *H. pylori* amongst the currently used regimens. A comprehensive literature search provided a data-base relating to the following treatments: dual therapy with an anti-secretory drug plus either amoxycillin or clarithromycin; standard triple therapy, with or without additional anti-secretory drugs; proton pump inhibitor triple therapy; and H_2-receptor antagonist triple therapy. Emphasis was placed on intention-to-treat analyses of eradication rates using all of the available evidence. The criteria used to select the optimal treatment were efficacy (eradication rates), frequency of side-effects, simplicity of the regimen (number of tablets per day and duration of treatment) and cost. The analysis showed that proton pump inhibitor triple therapy (that is, a proton pump inhibitor plus any two of amoxycillin, clarithromycin or a nitroimidazole) was the preferred treatment for the eradication of *H. pylori*. In particular, the 1-week, low-dose regimen with omeprazole plus clarithromycin plus tinidazole produced the highest eradication rates (>90%) with the lowest frequency of side-effects and at only modest cost.

Keywords: Helicobacter pylori, antibiotics, proton pump inhibitor

Introduction

Helicobacter pylori colonizes the gastric mucosa of approximately one-third of individuals in the Western world and most of the population in underdeveloped countries. While infection with *H. pylori* is frequently asymptomatic, this organism is not a harmless commensal. It is now generally agreed that *H. pylori* is responsible for the majority of cases of peptic ulcer and eradication therapy is widely acknowledged to be the preferred treatment for ulcer disease. Epidemiological studies report a strong association between *H. pylori* infection and the development of gastric cancer, findings which—if confirmed—have important implications particularly in countries with a high incidence of gastric malignancy. The data relating to non-ulcer dyspepsia are unclear, although it is likely that infection with *H. pylori* is related to this common condition in subgroups of dyspeptic patients. Furthermore, *H. pylori* has been implicated in the development of non-gastrointestinal disease—most notably ischaemic heart disease—and, whilst the relationship is tenuous, research continues in this field.

Given the high prevalence of *H. pylori* in the general population, together with the associations between the organism and some of the most common diseases currently afflicting societies worldwide, the impetus to discover an effective and acceptable treatment for this infection has been overwhelming. The almost inevitable outcome has been a plethora of concocted regimens and a multitude of clinical trials of varying quality, often yielding contradictory results, which has engendered a climate of confusion boardering on chaos.

Successful treatment of *H. pylori* infection is difficult to accomplish and, in general, requires combinations of two or more drugs. Three different types of therapeutic agents have been employed in the treatment of *H. pylori* infection: antibiotics, bismuth compounds and gastric anti-secretory drugs. While the efficacy of bismuth is likely to be related to direct antibacterial activity, the mechanism by which anti-secretory drugs assist in the eradication of the organism is unknown. Inhibition of gastric secretion removes the preferred acidic milieu of *H. pylori* yet proton pump inhibitors, which produce near neutral conditions in the stomach, given alone suppress but do not eradicate the organism; alternatively, anti-secretory drugs may alter the local action of co-administered antibiotics allowing improved penetration of the antibiotic to the site of infection.

The purpose of the present review is to provide an objective assessment of the relative merits of different therapies for the eradication of *H. pylori* based on a comprehensive examination of all of the currently available literature.

Literature review

Sources of data

A Medline literature search was carried out to identify publications relating to the treatment of *H. pylori* during the period January 1990 to October 1995. An additional manual search was performed for abstracts reporting the results of

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eradication therapy between 1992 and 1995 from meetings of the British Society of Gastroenterology, the American Association of Gastroenterology, the United European Gastroenterology Week and the World Congress of Gastroenterology, as well as the Annual International *H. pylori* meetings.

Selection of studies for inclusion

Papers or abstracts reporting eradication rates, defined as the absence of *H. pylori* on testing at least 1 month after stopping therapy, were included in the analysis of the following regimens:

(i) standard triple therapy consisting of bismuth plus a nitroimidazole plus either amoxycillin or tetracycline (with or without anti-secretory drugs);

(ii) dual therapy with an anti-secretory drug (either proton pump inhibitors or H_2-receptor antagonists) plus either amoxycillin or clarithromycin;

(iii) triple therapy with an anti-secretory drug (either proton pump inhibitors or H_2-receptor antagonists) plus any two of amoxycillin, clarithromycin or a nitroimidazole.

Studies with any of the following features were excluded from the analysis:

(i) review articles;

(ii) inadequate data;

(iii) regimens unspecified;

(iv) reported eradication rates pooled from two or more different regimens without specification of results for individual therapies;

(v) duplicate publications (identified by careful cross-checking of authors, locations, study characteristics and results);

(vi) assessment of *H. pylori* status less than 1 month after stopping eradication therapy.

Data analysis

Pooled eradication rates were calculated for each treatment group and for individual therapeutic regimens. Many studies reported the eradication rate as the number of patients eradicated divided by the number of patients available for assessment of *H. pylori* status 1 month after completing the course of treatment; this selective analysis, which excluded drop-outs and withdrawals, is similar to 'efficacy' or 'per protocol' analyses. However, more recent studies tended to report eradication rates according to intention-to-treat analysis. This is particularly appropriate for studies using complex regimens that are associated with a high frequency of adverse drug reactions as both these features tend to increase the number of withdrawals.

In the present review, the pooled eradication rates are presented in terms of an overall analysis, which includes the headline eradication rate reported in each study, and a separate intention-to-treat analysis. The latter analysis includes only those studies that either present the results as intention-to-treat eradication rates or provide sufficient details to allow calculation of intention-to-treat rates.

Of more than 1,500 publications examined, 352 studies satisfied the inclusion and exclusion criteria. Most of those excluded were duplicate publications. A total of 536 different treatment arms were included in the analysis of eradication rates for the particular regimens selected in the present review.

Dual therapy

Omeprazole plus amoxycillin

Of 121 studies reporting the eradication rates following treatment with omeprazole plus amoxycillin, 76% were published in abstract form and 53% were randomized controlled trials [1–121]. The overall eradication rate in a total of 5725 patients was 61% (95% CI 59–62). Intention-to-treat analysis showed that eradication of *H. pylori* was achieved in 59% (95% CI 58–61) in 4137 patients.

Factors affecting the eradication of *H. pylori* with omeprazole plus amoxycillin are shown in Table 1. In general, the eradication rates increased as the total daily dose of omeprazole increased. However, increasing the total daily dose of omeprazole from 40 mg to 80 mg increased the eradication rate by only 3% whilst doubling the cost of anti-secretory drug therapy. Little difference was observed between a single daily dose of omeprazole 40 mg and 20 mg twice daily. The total daily dose of amoxycillin appeared to be a more important determinant of eradication rates than that of omeprazole; increasing the dose of amoxycillin from <2 g day^{-1} to >2 g day^{-1} increased the eradication rate by almost 20%. Dual therapy for less than 2 weeks was associated with lower eradication rates than treatment for at least 2 weeks, while pre-treatment with omeprazole before the introduction of amoxycillin substantially reduced the eradication rates.

Table 1 Omeprazole + amoxycillin: factors affecting eradication rate.

	Number of patients eradicated	*Number of patients treated*	*% eradication (95% CI)*
Dose of omeprazole			
20 mg day^{-1}	211	408	52% (47–57)
40 mg day^{-1}	1504	2608	58% (56–60)
80 mg day^{-1}	494	813	61% (57–64)
120 mg day^{-1}	190	224	85% (80–89)
Single vs *divided doses of omeprazole*			
40 mg once daily	398	717	55% (52–59)
20 mg twice daily	912	1563	58% (56–61)
Dose of amoxycillin			
<2.0 g day^{-1}	481	964	50% (47–53)
2.0 g day^{-1}	1447	2402	60% (58–62)
>2.0 g day^{-1}	534	771	69% (66–72)
Duration of therapy			
<14days	370	682	54% (50–58)
≥ 14days	2092	3455	60% (59–62)
Pre-treatment with omeprazole			
yes	254	530	48% (44–52)
no	2208	3607	61% (59–63)

Overall, the results of therapy with omeprazole plus amoxycillin were unsatisfactory. Even when a sub-analysis was performed relating to 858 patients receiving omeprazole 40 mg day^{-1} in divided doses and amoxycillin 2 g day^{-1} for 2 weeks without pre-treatment with proton pump inhibitors, the intention-to-treat eradication rate achieved was only 62% (95% CI 59–65). Thus, excluding prohibitively expensive regimens that involve $\geq$120 mg of omeprazole per day—the overall results of which are heavily influenced by a single study [13]—eradication of *H. pylori* may be expected in less than two-thirds of patients treated with omeprazole plus amoxycillin.

Omeprazole plus clarithromycin

The results of 37 studies using omeprazole plus clarithromycin were reviewed. Eighty-four percent of the studies were published in abstract form and 46% were randomized controlled trials [26, 27, 36, 49, 54, 60, 74, 77, 81, 85, 100, 103, 106, 122–145]. The overall eradication rate in a total of 1837 patients was 70% (95% CI 68–72) while, according to an intention-to-treat analysis, *H. pylori* was eradicated in 68% (95% CI 65–70) of 1265 patients.

Factors associated with lower eradication rates in patients receiving omeprazole plus clarithromycin comprised lower doses of proton pump inhibitor, dual therapy for less than 2 weeks and pre-treatment with omeprazole. However, the success of therapy was inversely related to the total daily dose of clarithromycin, a finding that did not appear to be the result of confouding by other variables. In patients receiving omeprazole 40 mg day^{-1} plus clarithromycin for 2 weeks, without pre-treatment with omeprazole, the eradication rate for those receiving $\leq$1 g day^{-1} of clarithromycin was 75% (95% CI 70–81), compared with 65% (95% CI 61–69) for those given $>$1 g day^{-1}.

Although efficacy is superior to omeprazole plus amoxycillin, the eradication rates achieved with omeprazole plus clarithromycin are unsatisfactory, particularly when the cost of the antibiotic is taken into account.

Other dual therapies with anti-secretory drugs

Other proton pump inhibitors and H_2-receptor antagonists have also been used together with either amoxycillin or clarithromycin. Thirty-one studies were reviewed, of which 64% were randomized controlled trials [2, 3, 29, 45, 47, 82, 131, 146–169].

Cimetidine plus amoxycillin failed to eradicate *H. pylori* in two small studies while nizatidine plus either amoxycillin or clarithromycin produced eradication of the organism in 62–68%. Pantoprazole, in a single small study eradicated *H. pylori* in only 20% of patients treated.

Intention-to-treat analyses of pooled data relating to other dual therapies indicated an eradication rate with lansoprazole plus amoxycillin of 48% (95% CI 40–57), compared with 55% (95% CI 49–61) for lansoprazole plus clarithromycin, while similarly low efficacy was observed with ranitidine plus amoxycillin (46%: 95% CI 38–54) and ranitidine plus clarithromycin (59%: 95% CI 46–72). Hence, the data indicate that neither lansoprazole nor ranitidine, in combination with amoxycillin or clarithromycin, are suitable for the eradication of *H. pylori*.

Triple therapy

Standard triple therapy

Standard triple therapy refers to the combination of a bismuth compound plus a nitroimidazole plus either amoxycillin or tetracycline. The present review identified 143 studies which included 163 separate treatment arms of standard triple therapy [18, 25, 29, 31, 32, 37, 48, 57, 61, 65, 69, 76, 81, 86, 87, 90, 96–98, 105, 106, 120, 170–290]. Sixty-two percent of the studies were published in abstract form and 37% were randomized controlled trials. The overall eradication rate in 7979 patients was 81% (95% CI 81–82) compared with an intention-to-treat analysis which yielded an eradication rate of 78% (95% CI 77–79) in 6677 patients.

The combination of bismuth plus tetracycline plus a nitroimidazole achieved higher eradication rates (79%: 95%CI 77–80) than standard triple therapy with amoxycillin (71%: 95%CI 68–73). Addition of a proton pump inhibitor to standard triple therapy increased the pooled eradication rate with tetracycline-based regimens to 83% (95%CI 80–86) and with combinations including amoxycillin to 79% (95%CI 74–83). There was no difference in respect of the eradication rates between H_2-receptor antagonists and proton pump inhibitors added to standard triple therapy.

The effect of the duration of therapy on the eradication of *H. pylori* following standard triple therapy is shown in Table 2. Regardless of whether amoxycillin or tetracycline was used and irrespective of the presence or otherwise of anti-secretory drugs, the eradication rate after 7 days of treatment with standard triple therapy was no different from that following a 2 week course.

Many different doses of the individual constituents of standard triple therapy further complicate the analysis of eradication rates. In order to assess the effect of variations in doses, the regimens were categorized as shown in Table 3. There was little evidence that variations in the doses of antibiotics, within the ranges used in clinical trials, substantially affected the eradication rates achieved with standard triple therapy, either alone or in combination with anti-secretory drugs.

Overall, the data indicate that standard triple therapy effectively eradicates *H. pylori* in 70–80% of patients.

Table 2 Standard triple therapy: effect of treatment duration.

		% eradication rate (95% CI)	
		Bismuth + amoxycillin + nitroimidazole	*Bismuth + tetracycline + nitroimidazole*
7 days	alone	73% (67–78)	76% (72–81)
	+ASD	n/a	87% (84–90)
14 days	alone	76% (73–79)	77% (74–79)
	+ASD	82% (78–86)	83% (81–86)

ASD = anti-secretory drugs
n/a = insufficient data

Table 3 Standard triple therapy: effect of dose of antibiotics.

	% eradication rate (95%CI)			
	7 days		14 days	
	Alone	*+ASD*	*Alone*	*+ASD*
Bismuth + amoxycillin + nitroimidazole				
Rx1	84%*	n/a	80% (75–84)	n/a
Rx2	67% (62–73)	n/a	85% (78–91)	n/a
Rx3	74%*	n/a	80% (72–87)	n/a
Rx4	n/a	n/a	64% (56–73)	n/a
Bismuth + tetracycline + nitroimidazole				
Rx1	74% (70–78)	86% (82–90)	70% (65–74)	85% (80–90)
Rx2	87% (82–91)	87% (82–92)	80% (71–89)	83% (80–86)
Rx3	n/a	n/a	87% (84–91)	74% (63–85)
Rx4	n/a	n/a	78% (68–88)	87% (80–93)

Rx1 = bismuth + amoxycillin 2 g day^{-1} or tetracycline 2 g day^{-1} + nitroimidazole $\geq$1 g day^{-1}
Rx2 = as for Rx1 but amoxycillin 1.0–1.5 g day^{-1} or tetracycline 1.0–1.5 g day^{-1}
Rx3 = as for Rx1 but nitroimidazole (metronidazole or tinidazole) $<$1 g day^{-1}
Rx4 = as for Rx2 and Rx3
ASD = anti-secretory drugs n/a = data not available *insufficient numbers for 95% CI

Tetracycline offers a marginal benefit over amoxycillin and the evidence suggests that treatment for only 1 week is sufficient. However, whilst the addition of anti-secretory drugs produces a modest increase in the eradication rates, the extra cost involved and the even more complicated therapeutic regimen probably outweigh the benefits.

Proton pump inhibitor triple therapy

Triple therapy with a proton pump inhibitor plus two antibiotics was reported in 79 studies, 39% of which were randomized controlled trials [19, 27, 35–38, 40, 42, 44, 47, 50, 76, 77, 86, 89, 97, 103, 116, 124, 127, 128, 143, 145, 149, 150, 165, 210, 231, 262, 291–340]. There was no difference between overall eradication rate (87%: 95% CI 86–87) in a total of 5513 patients and that of the intention-to-treat analysis (86%: 95% CI 85–87) in 3389 patients.

Ten different regimens were studied (Table 4), eight of which achieved an eradication rate of $>$80% and those associated with lower rates had relatively small numbers of patients available for analysis. In the omperazole studies, the dose of proton pump inhibitor had no effect on the outcome, the eradication rates being 84% (95% CI 82–86) for omeprazole 20 mg day^{-1} and 86% (95% CI 85–88) for 40 mg day^{-1}. Similarly, in all studies of proton pump inhibitor triple therapy, the eradication rate was no different after a 1-week course of treatment (87%: 95% CI 85–88) than after a 2-week course (85%: 95% CI 82–87). Although the numbers of patients in studies using triple therapy with lansoprazole or pantoprazole were small, eradication rates were no different from those achieved with omeprazole regimens.

Individual proton pump inhibitor triple therapies that warrant particular attention are 1-week regimens associated with high eradication rates ($\geq$85%) based on large numbers of patients (Table 5). Apart from their high efficacy, each of these regimens are far less complicated than standard triple therapy. Moreover, the use of low-dose clarithromycin for short periods of time reduces the total cost of each treatment.

H_2-receptor antagonist triple therapy

The data relating to the eradication of *H. pylori* with an H_2-receptor antagonist plus two antibiotics were limited and the present review included only 23 studies, 62% of which were randomized controlled trials [40, 47, 65, 78, 145, 166, 175, 258, 320, 331, 335, 341–352]. The overall eradication rate in 814 patients was 72% (95%CI 68-75). Intention-to-treat analysis, which was available in only 436 patients, showed an eradication rate of 80% (95%CI 77-84).

The eradication rates achieved by the different H_2-receptor antagonist triple therapies, excluding those regimens for which no intention-to-treat analysis was available, are shown in Table 6. When used together with amoxycillin plus a nitroimidazole, ranitidine was less effective than omeprazole; however, in combination with clarithromycin plus a nitroimidazole, ranitidine appeared to give similar eradication rates to those achieved with omeprazole plus the same antibiotics. It is, though, to be noted that the numbers of patients in the H_2-receptor antagonist triple therapy studies were relatively small and the duration of treatment was usually 2 weeks or more.

Thus, while some of the H_2-receptor antagonist triple therapy regimens have yielded promising results, more data—particular in relation to the efficacy of 1-week courses of treatment—are required before this treatment can be recommended for the eradication of *H. pylori*.

Comparative studies

Dual therapies

Thirteen studies, seven of which were randomized controlled trials, directly compared omeprazole plus amoxycillin and omeprazole plus clarithromycin for the eradication of *H. pylori* [26, 27, 36, 49, 54, 60, 74, 77, 85, 100, 103, 106, 126]. Ten of the studies reported higher eradication rates with omeprazole plus clarithromycin, thus supporting the results of the earlier overall analysis of dual therapy regimens.

Table 4 Proton pump inhibitor triple therapy.

Regimen	*Number of patients eradicated*	*Number of patients treated*	*% eradication (95% CI)*
Omeprazole + amoxycillin + clarithromycin	382	442	86% (83–90)
Omeprazole + amoxycillin + metronidazole	953	1113	86% (84–88)
Omeprazole + amoxycillin + tinidazole	77	114	67% (59–76)
Omeprazole + clarithromycin + metronidazole	393	484	81% (77–85)
Omeprazole + clarithromycin + tinidazole	803	893	90% (88–92)
Lansoprazole + amoxycillin + clarithromycin	82	95	86% (79–93)
Lansoprazole + amoxycillin + metronidazole	78	88	89% (82–95)
Lansoprazole + amoxycillin + tinidazole	22	30	73%*
Lansoprazole + clarithromycin + metronidazole	68	73	93% (87–99)
Pantoprazole + clarithromycin + metronidazole	49	57	86% (77–95)

*insufficient data for 95% CI.

Table 5 Proton pump inhibitor triple therapy: individual 1-week regimens.

Regimen	*Number of patients eradicated*	*Number of patients treated*	*% eradication (95% CI)*
Omeprazole 40 mg day^{-1} Amoxycillin 2 g day^{-1} Clarithromycin 0.5 g day^{-1}	96	111	86% (80–93)
Omeprazole 40 mg day^{-1} Amoxycillin 1.5 g day^{-1} Metronidazole 1.2 g day^{-1}	181	212	85% (80–90)
Omeprazole 20 mg day^{-1} Clarithromycin 0.5 g day^{-1} Tinidazole 1.0 g day^{-1}	367	396	93% (90–95)
Omeprazole 40 mg day^{-1} Clarithromycin 0.5 g day^{-1} Tinidazole 1.0 g day^{-1}	413	461	90% (87–92)

Table 6 H_2-receptor antagonist triple therapy.

Regimen	*Number of patients eradicated*	*Number of patients treated*	*% eradication (95% CI)*
Ranitidine + amoxycillin + nitroimidazole	159	208	76% (71–82)
Ranitidine + clarithromycin + nitroimidazole	102	118	86% (80–93)
Roxatidine + amoxycillin + nitroimidazole	51	60	85% (76–94)

Four randomized controlled trials suggested that there was little difference between omeprazole plus amoxycillin and ranitidine plus amoxycillin in the eradication of *H. pylori* [2, 3, 29, 47]. However, in two of the studies, the eradication rates were exceptionally low with each regimen and, whilst the dose of omeprazole was 40 mg day^{-1} in

each study, the dose of ranitidine varied between 300 mg day^{-1} and 1800 mg day^{-1}. Thus, no definite conclusions can be drawn from these studies regarding the comparative efficacy of the two regimens.

Dual therapy vs *triple therapy*

Nineteen studies have compared the efficacy of standard triple therapy and dual therapy with omeprazole plus amoxycillin [25, 29, 31, 32, 48, 57, 61, 65, 69, 76, 86, 87, 90, 96–98, 105, 106, 120], eleven of which were randomized controlled trials; five studies included anti-secretory drugs in combination with triple therapy. In 15 of the studies, eradication rates were higher after triple therapy than following dual therapy (Figure 1), although considerable variation was observed in the difference between the two treatments.

The eradication rates with dual therapy (omeprazole plus either amoxycillin or clarithromycin) were compared with those with proton pump inhibitor triple therapy in 16 studies (including 17 comparisons), eleven of which were randomized controlled trials [19, 35, 36, 38, 40, 42, 44, 50, 76, 77, 89, 116, 124, 127, 143, 320]. Triple therapy achieved higher eradication rates than dual therapy in 16 studies (Figure 2).

Triple therapy

Although the previous overall analysis indicated that proton pump inhibitor triple therapy was more effective in the eradication of *H. pylori* than standard triple therapy, the results of six studies comparing the two therapies were inconclusive [37, 84, 128, 210, 231, 262]. However, while two small studies (with a total of only 51 patients) produced results in favour of standard triple therapy, three studies involving 942 patients reported higher eradication rates with proton pump inhibitor triple therapy. Thus, on balance, the comparative studies support the overall analysis.

The results of three comparative studies, two of which were randomized controlled trials, showed that standard triple therapy without the addition of anti-secretory drugs achieved higher eradication rates than H_2-receptor antagonist triple therapy [175, 258, 351]. Similarly, nine of ten comparative studies, which included eight randomized controlled trials, reported higher eradication rates with proton pump inhibitor triple therapy than with H_2-receptor antagonist triple therapy [40, 97, 103, 145, 318, 329, 333, 339, 348], a finding that supports the results of the overall analysis.

Side-effects of eradication therapy

Of the 352 studies of eradication therapy reviewed, 148 provided details of side-effects of treatment [1, 3, 4, 13, 14, 17, 21, 22, 27, 29, 32, 34, 35, 39, 42–44, 46, 50, 52, 54, 57–66, 74, 77–79, 82, 85, 87, 90, 92, 97, 100, 105, 106, 112, 113, 115, 118, 120, 123, 124, 127, 128, 130, 133–135, 140–142, 147–149, 151–153, 155, 156, 159, 161, 162, 164, 167, 171, 176, 180–183, 191, 193, 195, 196, 199, 206, 207, 211, 212, 216, 218–221, 223, 229, 230, 233–235, 240, 242, 246, 247, 249, 251, 252, 261–263, 265, 267, 269, 272, 273, 275, 279, 282, 285, 288, 290, 295–297, 300, 301, 308–310, 314, 317, 319, 320, 322, 324, 326, 327, 334, 340, 341, 343–346, 348, 350, 352]. Data relating to side-effects were also collected from a further ten studies which were excluded from the analysis of eradication rates [353–362]. Forty-nine percent of these 158 studies were randomized controlled trials.

As stated earlier, most of the studies of eradication therapy were published in abstract form and details relating to side-effects were frequently omitted. Thus, the present analysis may include a bias in favour of a higher frequency of side-effects because studies with few drug-related symptoms may have failed to include the relevant information in the abstract.

In the present review, data are presented in terms of the overall frequency of side-effects—mild, moderate or

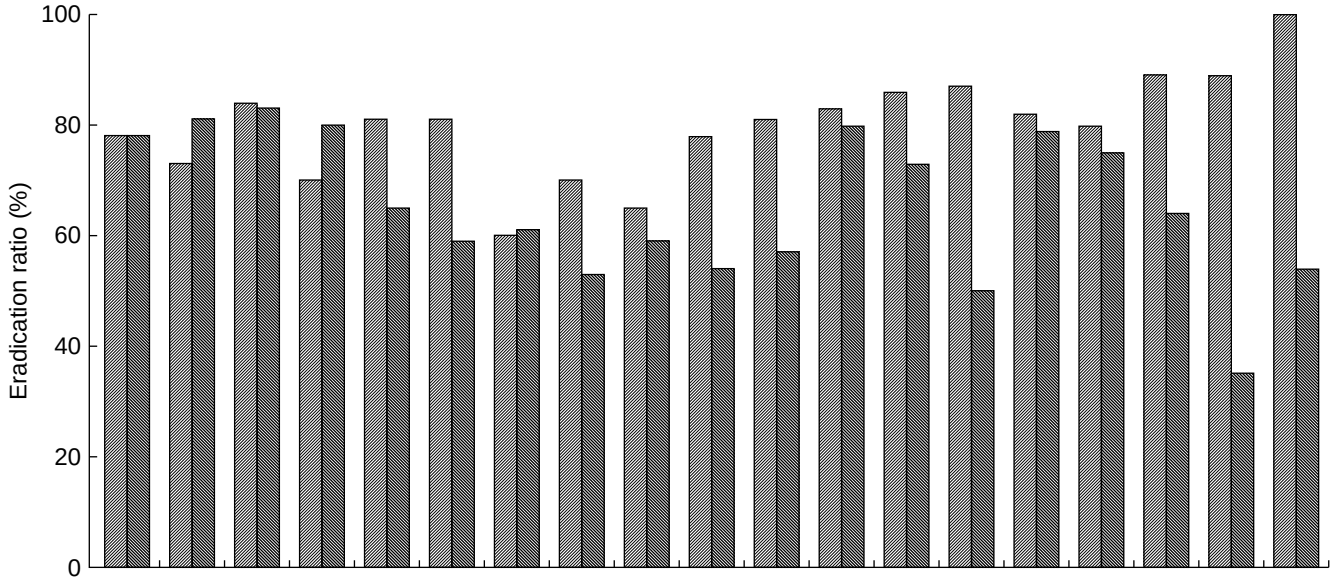

Figure 1 Nineteen studies comparing the eradication of *H. pylori* (%) in patients receiving dual therapy with omaprazole plus amoxycillin or standard triple therapy with bismuth plus a nitroimidazole plus either amoxycillin or tetracycline. ▨, standard triple therapy; ▧, omaprazole + amoxycillin.

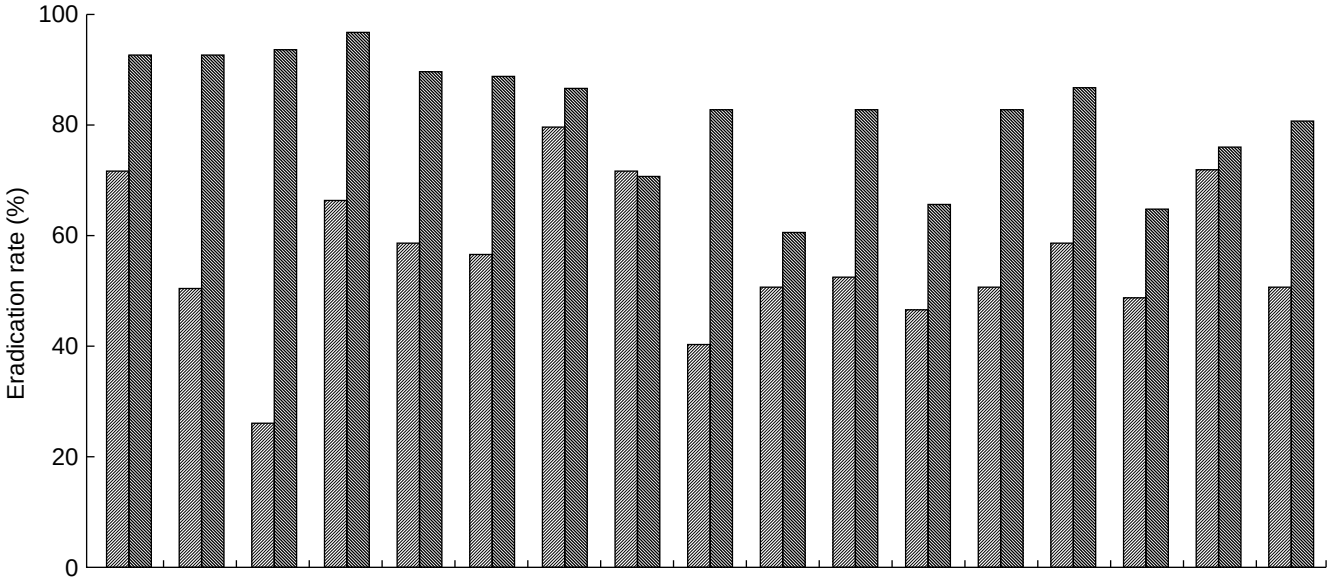

Figure 2 Seventeen studies comparing the eradication of *H. pylori* (%) in patients receiving dual therapy with a proton pump inhibitor plus either amoxycillin or clarithromycin, or triple therapy with a proton pump inhibitor plus two antibiotics (amoxycillin, clarithromycin or nitroimidazole).
▨, Proton pump inhibitors–dual therapy; ▧, Proton pump inhibitors–triple therapy.

severe—and the frequency of side-effects that were severe enough to prevent continuation of eradication therapy.

Dual therapy

The overall frequency of side-effects, regardless of severity, occurring during dual therapy with anti-secretory drugs plus a single antibiotic was 18% in a total of 3640 patients (Table 7). However, only 3% of patients experienced side-effects that were of sufficient severity to warrant withdrawal of therapy.

Omeprazole plus amoxycillin was associated with a lower frequency of side-effects than omeprazole plus clarithromycin although the proportion of patients having to stop therapy because of severe side-effects was similar. Data relating to H_2-receptor antagonists plus a single antibiotic were limited.

Triple therapy

One-third of 5751 patients treated with triple therapy experienced side-effects whilst treatment had to be withdrawn because of severe side-effects in 3% (Table 7).

Standard triple therapy was more frequently associated with both overall side-effects and severe drug-related symptoms resulting in cessation of treatment than other triple therapies. Regimens including tetracycline were more likely to produce side-effects than those with amoxycillin.

Proton pump inhibitor triple therapy was least likely to

Table 7 Side-effects during eradiation therapy.

	All side-effects % (95%CI)	*Side-effects stopping therapy % (95%CI)*
Dual therapy all studies	18% (17–19)	3% (2–3)
PPI dual therapy	19% (17–20)	3% (2–3)
Omeprazole + amoxycillin	14% (12–15)	2% (1–3)
Omeprazole + clarithromycin	26% (23–28)	3% (2–4)
Lansoprazole + clarithromycin	37% (29–45)	9% (5–12)
H_2-B dual therapy	11% (6–16)	2% (1–4)
Ranitidine + amoxycillin	8% (3–13)	1% (0–2)
Triple therapy all studies	33% (32–34)	3% (2–3)
Standard triple therapy	37% (35–39)	4% (3–5)
Bismuth + amoxycillin + nitroimidazole	23% (20–26)	5% (3–7)
Bismuth + tetracycline + nitroimidazole	40% (38–42)	4% (3–5)
PPI triple therapy	28% (26–30)	1% (1–2)
Omeprazole + amoxycillin + clarithromycin	22% (18–26)	1% (1–2)
Omeprazole + amoxycillin + metronidazole	39% (36–42)	2% (1–3)
Omeprazole + clarithromycin + tinidazole	7% (4–10)	0.4% (0–1)

PPI proton pump inhibitor
H_2-B H_2-receptor antagonist

produce symptoms resulting in withdrawal of treatment. In particular, low-dose omeprazole plus clarithromycin plus tinidazole was associated with overall side-effects in $<10\%$ of patients and rarely produced symptoms of sufficient severity to prevent continuation of treatment.

Comparative studies

Six studies reported the frequency of side-effects in patients receiving a proton pump inhibitor plus either amoxycillin or clarithromycin [54, 60, 77, 100, 106, 356]. Half of these studies showed that side-effects were substantially more frequent with clarithromycin dual therapy, a finding which is consistent with the overall analysis in Table 7.

Ten of eleven studies comparing dual therapy with standard triple therapy reported a markedly higher frequency of side effects in patients receiving triple therapy [29, 57, 61, 65, 87, 90, 97, 105, 106, 128, 251]. Similarly, in seven of eight studies, proton pump inhibitor triple therapy was more frequenty associated with drug-related symptoms than dual therapy [27, 35, 42, 44, 77, 97, 128, 149].

Compliance with eradication therapy

Considering the enormous number of publications of eradication therapy, data relating to therapeutic compliance are sparse. The present review identified 39 studies, including 50 different treatment arms, which reported compliance with various eradication therapies [3, 4, 34, 46, 54, 57, 63–66, 92, 100, 113, 123, 172, 174, 177, 178, 191, 195, 203, 210–212, 235, 249, 295, 300, 308, 310, 341, 357, 363–369]. In 16 studies, the method used to measure compliance was not specified, usually because the data were presented in abstract form only. Of the remaining 23 studies, compliance was assessed by tablet counts in 19 and by interviewing the patients in four studies.

No standard format was used for reporting compliance. The least specific approach was an unquantified comment that 'compliance was high'. Some studies reported compliance in terms of a solitary percentage; others gave the proportion of patients with poor compliance; in neither was the term defined. However, the most acceptable, and the most frequently used, approach was to describe compliance in terms of the percentage of patients who took more (or less) than a specified proportion of the prescribed medication. Unfortunately, because the proportion of medication which was selected as the demarcation level varied widely amongst studies, the data from different reports cannot be compared. As a result, only vague conclusions may be drawn from the data relating to compliance.

Of the 16 studies which commented on compliance with dual therapy—that is, an anti-secretory drug plus a single antibiotic—only one reported poor compliance. Similarly, none of 29 studies relating to patients receiving triple therapy reported unsatisfactory compliance. In general, it appears that compliance with either dual or triple therapy is satisfactory in $>90\%$ of patients.

Five studies of dual therapy and four studies of triple therapy reported a markedly reduced eradication rate in patients with poor compliance compared with those who took medication regularly.

Metronidazole resistance

Many studies have reported that the presence of metronidazole-resistant *H. pylori* reduces the efficacy of eradication regimens which include a nitroimidazole antibiotic [183, 193, 197, 220, 228, 234, 235, 247, 297, 339, 345, 354, 370–374]. However, whilst the number of patients in the metronidazole-sensitive groups are frequently large, most of these studies have only a small number of patients with *H. pylori* which are resistant to metronidazole. Moreover, there is considerable variation in the effect of metronidazole resistance on the eradication rates, both within the same treatment groups and amongst different therapies.

Of the regimens reviewed in the present study, most of the data available on the effect of metronidazole resistance relate to standard triple therapy. In fourteen studies, the eradication rate in patients with metronidazole-resistant *H. pylori* receiving standard triple therapy without anti-secretory drugs varied between 0% and 96% and, in 13 of the studies, eradication was higher when the organism was sensitive to nitroimidazoles. Pooling the data from each study, the eradication rate with metronidazole-sensitive *H. pylori* was 86%, compared with 58% with metronidazole-resistant organisms (Table 8). It is to be noted that the pooled data were heavily influenced by a single large study which reported an eradication rate of 87% in 140 patients with metronidazole-resistant *H. pylori* [370].

Four studies reported the effect of metronidazole resistance on the eradication rates achieved with proton pump inhibitor triple therapy. *H. pylori* was eradicated in 99% of patients with metronidazole-sensitive organisms compared with 69% of those with metronidazole resistance (Table 8). These

Table 8 Effect of metronidazole resistance on eradication rates with triple therapy (pooled results from 19 studies).

	Metronidazole-sensitive		*Metronidazole-resistant*	
	Number Treated	*% eradication rate (95%CI)*	*Number Treated*	*% eradication rate (95% CI)*
Standard triple therapy	787	86% (84–89)	322	58% (53–64)
Proton pump inhibitor triple therapy	153	99% (97–100)	120	69% (61–77)
H_2-receptor antagonist triple therapy	66	95% (90–100)	10	40%*

All regimens included either metronidazole or tinidazole
*insufficient data for 95% CI

results, assuming a prevalence of metronidazole resistance in Western countries of 15–25%, are consistent with the earlier overall analysis of proton pump inhibitor triple therapy which showed an eradication rate of 86%. However, whilst the evidence suggests that there is a link between antibiotic resistance and eradication failure with these regimens, metronidazole resistance does not appear to lessen the overall efficacy of proton pump inhibitor triple therapy to any important extent.

H_2-receptor antagonist triple therapy also produced high eradication rates in patients with metronidazole-sensitive *H. pylori*. However, the data relating to metronidazole-resistant organisms were sparse.

Recent developments in eradication therapy

The present review includes studies published up to the Autumn of 1995 and, since that time, no major developments in the field of eradication therapy have appeared in the literature. Reports published in the proceedings of the Spring meeting of the British Society of Gastroenterology and the American Gastroenterological Association confirm the efficacy of omeprazole-based triple therapies and also indicate that regimens comprising lansoprazole plus two antibiotics are equally effective.

During the past year, ranitidine bismuth citrate—used in combination with either amoxycillin or clarithromycin—has been licensed for the treatment of *H. pylori* infection. However, as a recent review of ranitidine bismuth citrate concluded [375], it is difficult to justify the use of eradication regimens involving this new drug. Claims that ranitidine bismuth citrate plus clarithromycin yield high eradication rates are based on small numbers of patients; in addition, only patients whose duodenal ulcers had healed were included in the eradication analysis and, given that unhealed ulcers are associated with persistence of *H. pylori* [376], the likely effect of excluding patients with unhealed ulcers is to inflate falsely the reported eradication rates. Moreover, despite significant proportions of patients failing to be included in the assessment of eradication, no intention-to-treat analysis of all patients recruited to the trials was provided. Thus, with the uncertain efficacy of these regimens, together with the recommended duration of treatment for 4 weeks and the high cost of such treatment, there appears to be no indication to prefer ranitidine bismuth citrate regimens to the more established eradication therapies described earlier.

Comparing eradication therapies

Few areas of therapeutics have been investigated as thoroughly as the treatment of *H. pylori* infection. Yet, despite an abundance of data, controversy still persists regarding the eradication therapy of choice. This, of course, is in no small part due to the vested interests vying for supremacy in this lucrative field. Given the large number of studies and the complexity of the data base, it is an easy matter to be selective in the choice of publications in order to support one particular eradication regimen at the expense of others: the scientific principle that conclusions should be based on all of the relevant evidence has repeatedly been ignored. The purpose of the present review is to provide an objective analysis of all of the available data before drawing conclusions concerning the relative merits of different eradication regimens.

Criteria for selection of eradication therapy

(i) *Efficacy* In recent years, there has been a trend towards reporting eradication rates in terms of an intention-to-treat analysis. As discussed earlier, this is preferable to the method of restricting analysis to only those patients who complete treatment and return for follow-up visits, an approach which inflates the success rates beyond that to be expected in routine medical practice. Of similar importance is the total number of patients treated; this is crucial for the reliability of the estimate of eradication. Most of the regimens analysed in the present review have been used in a large number of patients and, consequently, the pooled eradication rates are likely to be accurate.

Excluding serious toxicity—for which there is no evidence—efficacy is the most important criterion for the selection of therapy. The present analysis clearly demonstrates the differences in eradication rates amongst the various therapies for *H. pylori* infection.

(ii) *Side-effects* Side-effects would be of primary importance if they resulted in serious illness or adversely affected the efficacy of treatment in a substantial proportion of patients, neither of which appears to be the case with eradication therapies. Concerns about the development of pseudomembranous colitis with eradication therapy have not materialised and there are only a few reports of individual patients suffering from this serious complication of antibiotic therapy. Although side-effects are common, most patients are able to complete the course of eradication therapy and there is little evidence that mild side-effects reduce adherence. Hence, side-effects are of secondary importance and influence the selection of eradication therapy only if the application of other criteria—in particular, efficacy—yield equivalent results with different regimens.

(iii) *Simplicity* A simple and convenient regimen would involve a small number of tablets taken each day, preferably as a single dose, for a short period of time. Unfortunately, all current eradication regimens involve multiple daily dosing. However, there are marked differences between the various eradication regimens, in terms of both the number of tablets per day and the total duration of treatment, factors which should be taken into account in the selection of eradication therapy.

(iv) *Compliance* Although compliance with treatment is perceived to be a problem during eradication therapy, the data from clinical trials do not support this view. Furthermore, the data do not indicate any difference in compliance between the various eradication therapies and, consequently, this criterion is not of value in choosing between regimens.

(v) *Cost* Eradication therapies vary widely in cost—for example, high dose omeprazole plus clarithromycin is more than ten times as expensive as standard triple therapy. Provided that treatments are similar according to other

criteria, it is appropriate for financial considerations to influence the selection of a particular eradication regimen.

Eradication therapy of choice

A rational approach to the selection of eradication therapy is the application of the above criteria to all of the data in the present review relating to regimens with substantial numbers of patients available for analysis (Table 9).

The benefits of dual therapy with omeprazole plus amoxycillin—in other words, a low frequency of side-effects and a small number of tablets per day—are heavily outweighed by its disadvantages: it requires a minimum of 2 weeks of treatment, is relatively expensive and, most of all, produces unacceptably low eradication rates. Omeprazole plus clarithromycin, while yielding marginally higher eradication rates than omperazole plus amoxycillin, is more likely to be associated with side-effects and is considerably more expensive; moreover, as secondary clarithromycin resistance is a common characteristic of treatment failure, regimens which include clarithromycin but which are associated with low eradication rates are likely to increase the prevalence of *H. pylori* resistance to this antibiotic. Given these considerations, the use of dual therapy with omeprazole plus either amoxycillin or clarithromycin cannot be recommended.

The obvious advantages to standard triple therapy are the wide experience in clinical trials involving $>7{,}000$ patients and the low cost. On the other hand, the disadvantages are equally striking: a complicated regimen involving numerous tablets each day, a high frequency of side-effects and a likely success rate of $<80\%$. The addition of an anti-secretory drug to standard triple therapy, often referred to as 'quadruple therapy', increases the number of tablets and the cost of treatment, does not lessen side-effects but is associated with a small increase in the eradication rate. However, adding an extra drug to an already complicated regimen—when other, even more effective therapies with fewer disadvantages are available—is perverse, except in rare cases where patients have multiple allergies to antibiotics.

As shown in Table 9, proton pump inhibitor triple therapies offer high eradication rates with short-term courses of less complicated treatment. In particular, the 1-week, low-dose regimen with omeprazole plus clarithromycin plus tinidazole is the most effective therapy for the eradication of *H. pylori*, requires fewer tablets per day than any other regimen and is associated with the lowest frequency of side-effects.

Thus, when all of the relevant data are taken into consideration, the argument in favour of proton pump inhibitor triple therapy being the treatment of choice for the eradication of *H. pylori* is overwhelming.

The approach adopted in the present review is in keeping with the current interest in evidence-based medicine. It exposes the capricious nature of those decisions defended on the grounds of personal experience and curtails the influence of those with a vested interest in promoting a partial interpretation of facts. It does, though, pose difficulties for the introduction of new eradication therapies: data are necessarily limited in the early stages of clinical trials and, as a result, this militates against a recommendation for the use of such therapy in routine medical practice until the treatment has been tested in multiple studies involving large numbers of patients. Nevertheless, if patients are to receive the optimal therapy for their illness and if the resources of the NHS are to be used prudently, an objective assessment

Table 9 Selection of eradication therapy.

Regimen	*Eradication rate*	*Side-effects all*	*Side-effects serious*	*Duration of therapy*	*Number tablets/day*	*cost*
Dual therapy						
Omeprazole 40 mg day^{-1} + amoxycillin 2 g day^{-1}	60%	14%	2%	14 days	6	~£40
Omeprazole 40 mg day^{-1} + clarithromycin 1 g day^{-1}	68%	26%	3%	14 days	6	~£80
Standard triple therapy						
Bismuth 480 mg day^{-1} + tetracycline 2 g day^{-1} + metronidazole 1.2 g day^{-1}	78%	40%	4%	7 days	15	~£15
Bismuth 480 mg day^{-1} + tetracycline 2 g day^{-1} + metronidazole 1.2 g day^{-1} + omperazole 40 mg day^{-1}	86%	40%	4%	7 days	16	~£30
Proton pump inhibitor triple therapy						
Omeprazole 40 mg day^{-1} + amoxycillin 1.5 g day^{-1} + metronidazole 1.2 g day^{-1}	85%	39%	2%	7 days	8	~£25
Omeprazole 40 mg day^{-1} + amoxycillin 2 g day^{-1} + clarithromycin 0.5 g day^{-1}	86%	22%	1%	7 days	8	~£30
Omeprazole 20 mg day^{-1} + clarithromycin 0.5 g day^{-1} + tinidazole 1 g day^{-1}	>90%	7%	<1%	7 days	5	~£30

of all of the data from clinical trials should be the foundation of therapeutic decisions.

Conclusions

The purpose of the present review of the literature is to provide the conditions for an informed and objective judgement of the competing claims of different therapies for the eradication of *H. pylori*. Emphasis is placed on the importance of a fundamental principle of science, *viz*. that conclusions should be based on all of the available evidence. Furthermore, the review proposes a set of criteria to be applied to the total data for each individual regimen in order to determine impartially the eradication therapy of choice.

The analysis is unequivocal: the preferred treatment for the eradication of *H. pylori* is proton pump inhibitor triple therapy. In particular, low-dose therapy with omeprazole plus clarithromycin plus tinidazole achieves high eradication rates with a relatively simple regimen associated with few side-effects and at modest expense.

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