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The European meeting on *Helicobacter pylori*: therapeutic news from Lisbon

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Summary
The current standard of *Helicobacter pylori* treatment has been confirmed by the studies presented at the Lisbon workshop—that is, one of three one week proton pump inhibitor (PPI) based triple therapies comprising a twice daily standard dose of a PPI in combination with two of the following antimicrobial agents: clarithromycin, amoxycillin, or a nitromidazole. This standard of treatment is also highly efficacious and cost-effective in routine community practice. The current data confirm the equivalence of ranitidine bismuth citrate to PPI, and of azithromycin to clarithromycin. The optimum dose for azithromycin has not yet been defined. There is some evidence that in certain regions treatment for more than one week may be advantageous. The reasons are still not clear. However, microbial resistance may be one important factor, as it has a substantial effect on treatment outcome and the prevalence of resistance varies considerably in different areas. The negative impact of resistance is increased by shortening the treatment time. At present, there is no general necessity to test for resistance before treatment. However, before selection of a second line treatment, testing for resistance is recommended.

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Introduction

With the advent of proton pump inhibitor (PPI) based triple therapies initiated by Bell *et al*[1] and Bazzoli *et al*[2], a new standard of *Helicobacter pylori* treatment efficacy has been set. This has been recently integrated into the recommendations of the Maastricht Consensus Report 1996.[3] On 12–14 September 1997, Lisbon hosted the Xth International Workshop on Gastroduodenal Pathology and *Helicobacter pylori*, the official international meeting of the European *Helicobacter pylori* Study Group. A section of this meeting has traditionally been devoted to therapy, and this year it comprised 67 accepted abstracts.

Abstracts addressing the following issues are reviewed. Are any alterations of the dosage, the duration or the number of agents able to optimise the current standard? Is the application of the standard in routine practice as efficacious as in scientific studies and is it cost-effective? What are the predictors of treatment success? Emphasis is placed on microbial resistance which leads to the issue of second line treatment.

Forty two abstracts presented original data on therapeutic trials with 54 treatment arms. The results of seven day treatment arms grouped for the main combinations of antimicrobial agents are given in figures 1–3.[4–23]

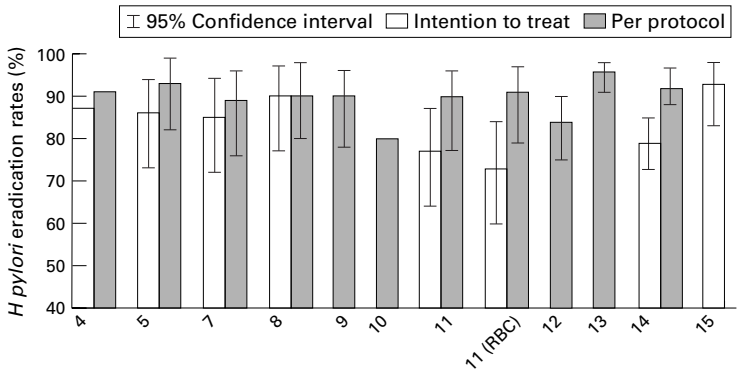

Figure 1 Helicobacter pylori eradication rates with triple therapy comprising proton pump inhibitor (RBC = ranitidine bismuth citrate), clarithromycin, and a nitroimidazole for seven days. The numbers of the references from which the data are taken are given on the x axis.

Is more better?

DOSE OF MACROLIDE

The optimum dose of clarithromycin in PPI triple therapies is still debatable, as randomised studies indicate that, on the one hand, the minimum dose is different depending on the other components,[24 25] and, on the other, side effects such as taste disturbances and diarrhoea are controlled mainly by the dose.[24 25]

The dose of clarithromycin was the subject of a meta-analysis by Huang *et al*.[26] Analysing 26 treatment arms of one week triple therapies with PPI, clarithromycin, and metronidazole, they found that 500 mg clarithromycin twice a day resulted in a significantly higher *H pylori* cure rate (90% intention to treat (ITT)) than 250 mg twice a day (82% ITT). The same holds true for the triple therapy with PPI, clarithromycin, and amoxycillin (91% *v* 80% ITT). A drawback of this meta-analysis is that no data were provided on the randomisation. An earlier randomised study indicated that 250 mg clarithromycin is equivalent in the combination PPI, clarithromycin, and metronidazole.[24] When used in combination with lansoprazole and amoxycillin, Yang *et al*[10] found that 250 mg clarithromycin was satisfactory only when used for two weeks (92% per protocol (PP)), but 500 mg was still more effective (96% PP). Clarithromycin in combination with a PPI and a nitroimidazole may be replaced by azithromycin without loss of efficacy. Whereas Caselli *et al*[27] achieved a 93% eradication rate using azithromycin 500 mg for three days, Seelis *et al*[28] achieved only 47% with the same dose, but 93% using azithromycin 500 mg for six days.

DOSE OF ACID SUPPRESSIVE AGENT

The Maastricht Consensus Report recommends twice daily standard doses of the PPI in PPI triple therapy whereas Bazzoli *et al*[2]

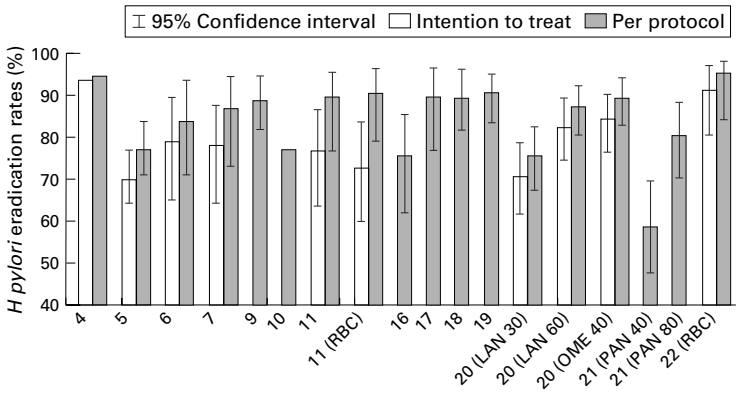

Figure 2 Helicobacter pylori eradication rates with triple therapy comprising proton pump inhibitor (RBC = ranitidine bismuth citrate), clarithromycin, and amoxycillin for seven days. The numbers of the references from which the data are taken are given on the x axis. LAN 30, lansoprazole 15 mg twice daily; LAN 60, lansoprazole 30 mg twice daily; OME 40, omeprazole 20 mg twice daily; PAN 40, pantoprazole 40 mg once daily; PAN 80, pantoprazole 40 mg twice daily.

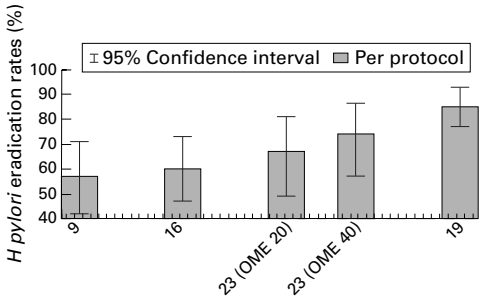

Figure 3 Helicobacter pylori eradication rates with triple therapy comprising proton pump inhibitor, amoxycillin, and metronidazole for seven days. The numbers of the references from which the data are taken are given on the x axis. OME 20, omeprazole 20 mg once daily; OME 40, omeprazole 40 mg once daily.

originally used a once daily standard dose. Three abstracts of large studies investigating the dose of PPI clearly support the Maastricht recommendation. In a randomised study by Buda *et al*,[20] two daily doses of 30 mg lansoprazole proved to be significantly more efficacious (88% PP, 83% ITT) than 15 mg twice a day (76% PP, 71% ITT) in combination with clarithromycin and amoxycillin. Applying the same antibiotics in a randomised study, Lamouliatte *et al*[21] found pantoprazole 40 mg to be significantly superior when used twice a day (81% PP) compared with a once daily dosage (59%). In combination with metronidazole and amoxycillin, omeprazole 40 mg yielded a higher *H pylori* cure rate (74%) than omeprazole 20 mg (67%).[23] Further evidence was provided that 400 mg ranitidine bismuth citrate is equivalent to a standard dose of PPI in triple therapy.[11 14 22 29] In dual therapy with clarithromycin it may be even superior to PPI.[29]

Is longer better?

The issue of treatment duration turned out to be rather controversial in the Lisbon abstracts. Most studies confirmed that one week of treatment is sufficient in PPI triple therapy, but there may be some exceptions that are potentially due to regional differences or disease entity. No benefit from a longer treatment period was found in the following studies: in Italy with ranitidine bismuth citrate and clarithromycin, 7 *v* 14 days[30]; in the USA with lansoprazole, clarithromycin, and amoxycillin, 10 *v* 14 days[31]; in Spain with omeprazole, clarithromycin, and amoxycillin, 6 *v* 12 days for peptic ulcer disease[32]; and in Germany with pantoprazole, clarithromycin, and metronidazole 7 *v* 14 days.[12] Significantly higher *H pylori* cure rates with longer treatments were achieved in Croatia[16] with omeprazole, amoxycillin, and metronidazole as well as with omeprazole, clarithromycin, and amoxycillin (7 *v* 14 days), in Spain with omeprazole, clarithromycin, and amoxycillin (6 *v* 12 days) for patients with non-ulcer gastritis,[32] and in Taiwan[10] with lansoprazole, clarithromycin 250 mg once daily, and amoxycillin (7 *v* 14 days). In the last of these studies, however, the dose of clarithromycin used was below the standard. None of these studies provided data on resistance. In contrast, reducing treatment duration to less than one week has proved to be disadvantageous.[28 33 34]

Are more agents better?

Authors presenting studies on quadruple or even quintuple therapies intended to increase the eradication rate further, to reduce the treatment time, or to establish a second line treatment after failure of *H pylori* eradication. No convincing data have been provided to support the notion that the use of more than three agents is superior as a first line treatment in eradicating *H pylori*.

The quadruple therapy of PPI, bismuth, metronidazole, and tetracyclin, introduced by Hosking *et al*,[35] de Boer *et al*,[36 37] and Borody *et al*,[38] is highly efficacious when used as an initial treatment and when the high numbers of tablets are taken for one week. Reducing the treatment duration to four or two days has now been shown to lead to a loss of efficacy, particularly in patients harbouring a metronidazole resistant strain.[33 34]

A treatment introduced by Daskalopoulos *et al*[39] using the five agents colloidal bismuth subcitrate, tetracyclin, metronidazole, roxithromycin, and lansoprazole resulted in a higher eradication rate than with three or four of these agents, but the rate achieved did not exceed 92% PP. Moreover, the agents were given for two weeks and no data on side effects were presented.

After failure of dual therapy, the combination of omeprazole with not only two but all three standard antimicrobial agents, all given for five days, was no more efficacious (93% PP, 90% ITT) than omeprazole, clarithromycin, and metronidazole for seven days.[8] Another two groups presented studies on newly created quadruple therapies as second line treatments. The eradication rates were satisfactory for a second line treatment: omeprazole, azithromycin, amoxycillin, and colloidal bismuth subcitrate for two weeks (81% PP, 77% ITT)[40]; omeprazole, metronidazole, amoxycillin, and bismuth citrate for two weeks (82% PP, 70% ITT).[41] However, in both studies no data on the initial treatment or the pattern of microbial resistance after treatment failure were given. The former therapy was reported to be linked

to a side effect rate of 41%.[40] Moreover, the question of safety of quadruple therapy was further raised by Phillips *et al*,[42] reporting high blood levels of bismuth in two of eight patients after co-administration of colloidal bismuth subcitrate and omeprazole for two to four weeks, but not after bismuth subnitrate/carbonate and omeprazole.

Is treatment efficacious and cost-effective in routine community practice?

Two studies ascertained that *H pylori* eradication rates are similar[43] or even equivalent[44] in the community setting to clinical trials. A cost analysis was performed by Vakil and Fennerty[43] using a decision tree model with a follow up period of two years. The costs are dominated by cases of failed eradication, but not by the initial costs of treatment. Therefore highly efficacious treatments such as PPI based triple therapies resulted in the lowest total costs, the triple therapy with a PPI, clarithromycin, and metronidazole being the most cost-effective. Regimens with eradication rates of less than 90% are not cost-effective in routine practice.

Is treatment efficacy dependent on disease entity?

The GU-Mach study[6] and also the study by Katicic *et al*[16] confirmed comparable *H pylori* eradication rates in the treatment of gastric and duodenal ulcer.[7] Comparing *H pylori* eradication in peptic ulcer disease and non-ulcer dyspepsia, two studies[19 32] detected lower eradication rates in the treatment of non-ulcer dyspepsia. No possible reasons are given, but lower compliance may be the cause. Georgopoulos *et al*[45] found no difference between ulcer disease and non-ulcer dyspepsia, but lymphoid follicles were a negative predictor of treatment success. Again, it was confirmed that healing of uncomplicated duodenal ulcer is achieved by an effective one week *H pylori* treatment without consecutive acid suppression.[9 46–49] In contrast, gastric ulcer healing may take a long time despite continued PPI therapy.[6 47]

What is the impact of microbial resistance?

The reported prevalences of pretreatment resistance were similar to previous reports from Europe: macrolide resistance about 2–3%; nitroimidazole resistance about 30%.[4 23 50 51] Exceptions were metronidazole resistance in Greece of 44%,[45] macrolide resistance in France of 10.5%[21] or about 15%,[29] and an increase in macrolide resistance in Portugal from 5.6% (1990–1993) to 11.2% (1994–1997) in the past seven years.[51]

The impact of metronidazole resistance on eradication rates was confirmed. In the face of metronidazole resistance, *H pylori* eradication rates were 75%[4] and 74%[50] when a triple therapy with PPI, clarithromycin, and metronidazole was used, and 62% when a four day quadruple therapy was used.[34] In a dual antibiotic treatment without a PPI, the impact of metronidazole resistance is considerably greater.[4] Poor eradication of less than 50% ensues when clarithromycin resistance is present.[4 50] In contrast, Mégraud *et al*[29] reported an *H pylori* cure rate of 11 in 12 cases with clarithromycin resistant strains using dual therapy with clarithromycin and ranitidine bismuth citrate.

Again confirmed, although in small numbers, was the occurrence of post-treatment resistance to clarithromycin in 50%[4] or more[50 52] of cases with failure after macrolide containing regimens.

Whereas second line treatment of patients with persistent *H pylori* infection after dual therapy with omeprazole and amoxycillin is highly efficacious with triple therapy,[8] second line treatment after failure of triple therapy still yields inconsistent and partly unsatisfactory results. The recommended quadruple therapy with PPI, bismuth, metronidazole, and tetracyclin led to eradication rates of 72%,[53] 50%,[52] and 93%,[17] whereas with the modified quadruple therapies mentioned above the eradication rates were higher (81%,[40] 82% and 86%[41]). Almost all of the studies on second line therapies specified neither the initial therapy nor the pattern of resistance after initial treatment failure. Obviously, the success of the second line treatment depends on the components of the initial treatment.[54] Thus no general conclusion can be drawn from the studies presented on second line treatments. However, it has been confirmed that it is of benefit to determine the resistance status before planning the second line treatment.[50 52] A small study[55] reported a 75% eradication rate with omeprazole, amoxycillin, and ciprofloxacin in cases with double resistance against clarithromycin and metronidazole. This needs further confirmation, as previous experience with ciprofloxacin in *H pylori* eradication therapy has been very poor.

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