

Management of *Helicobacter pylori* eradication – the influence of structured counselling and follow-up

F. A. Al-Eidan,¹ J. C. McElnay,¹ M. G. Scott² & J. B. McConnell³

¹School of Pharmacy, The Queen's University of Belfast, 97 Lisburn Road, Belfast BT7 1PT, ²Antrim Hospital Academic Pharmacy Practice Unit, Antrim Area Hospital, Bush Road, Antrim BT41 2RL and ³Department of Medicine, United Hospital Group Trust, Bush Road, Antrim BT41 2RL

Aims *Helicobacter pylori* (*H. pylori*) eradication rate varies according to the treatment regimen used and other factors, e.g. antimicrobial resistance and patient compliance. The aim of the present study was to evaluate the influence of patient counselling and follow-up on *H. pylori* eradication rates and to document the effectiveness of a 1 week eradication regimen consisting of lansoprazole (30 mg once daily), amoxicillin (1 g twice daily) and clarithromycin (500 mg twice daily).

Methods Seventy-six dyspeptic patients, who at endoscopy were found to have gastritis, duodenitis or ulceration, and a positive *H. pylori* urease test, were recruited. Patients were randomly assigned to an intervention group ($n=38$) or a control group ($n=38$). Intervention patients received their medicines via the hospital pharmacy and were counselled (and followed up) by a hospital pharmacist. Control patients were given a standard advice sheet and referred to their GP who prescribed the same therapy.

Results Intervention patients exhibited a statistically significant improvement in the *H. pylori* eradication rate (94.7% vs 73.7%; $P=0.02$) and compliance (92.1% vs 23.7%; $P<0.001$). Of the 64 *H. pylori* eradicated patients, 62 were able to eliminate their antisecretory medication compared with only 12 of the *H. pylori* persistent patients ($P<0.001$). A pharmacoeconomic evaluation indicated that counselling and follow-up reduced the direct costs of eradication by approximately £30 per patient.

Conclusions Structured patient counselling and follow-up can have a significant effect on *H. pylori* eradication rates and should be a routine part of therapy.

Keywords: *H. pylori*, patient counselling, peptic ulcer disease

Introduction

Helicobacter pylori (*H. pylori*) infection of the mucosa of stomach and duodenum has been positively associated with gastritis, duodenal ulcer, gastric ulcer and gastric carcinoma [1–3].

Although antisecretory drugs have been shown to heal ulcers, once treatment is withdrawn almost all ulcers can be expected to recur within 2 years. Eradication of *H. pylori* significantly decreases ulcer recurrence rates and the complications associated with ulcer disease [4]. Several consensus groups therefore recommend that all patients

with peptic ulcers associated with the presence of *H. pylori* should be treated with antimicrobial agents to eradicate the bacteria [5]. Several combinations of antimicrobial agents and antisecretory drugs have been used in clinical trials to date. The best results have been achieved with triple therapies, however, the results have been variable, possibly due to differences in patient compliance and bacterial resistance to the antimicrobial agents used [6–10].

Patient compliance is an important factor in the successful outcome of any therapeutic programme [11, 12] and the critical effect of compliance on the efficacy of triple therapy for *H. pylori* has been demonstrated [13]. One major factor predisposing to poor patient compliance is lack of proper counselling on the part of medical and paramedical staff [14–16].

The main aim of the present study was to evaluate, in a randomized controlled trial in one centre, the influence of

Correspondence: Professor James C. McElnay, School of Pharmacy, The Queen's University of Belfast, 97 Lisburn Road, Belfast BT9 7BL.

Received 15 March 2001, accepted 21 September 2001.

patient counselling and follow-up on *H. pylori* eradication rate and patient outcomes. A second goal of the study was to evaluate the effectiveness and tolerability of an eradication regimen consisting of lansoprazole, amoxicillin and clarithromycin.

Methods

Study site

The study was conducted at the endoscopy unit of the Antrim Area Hospital (a 378-bed district hospital).

Study design

This was a prospective, randomized, controlled study.

Patients

All adult patients who were referred by their GP for investigation of dyspepsia, by outpatient referral to the GI clinic or open access referral to the Endoscopy Unit, Antrim Area Hospital, and who endoscopically were found to have macroscopic changes of gastritis, duodenitis or ulceration, with the presence of *H. pylori* in the stomach, using a rapid urease test (ClotestTM, Delta West Pty Ltd, Australia), were invited to participate in the study. Those patients who gave their informed consent to participate in the study were enrolled. Consent was verbal due to the sensitivity of patient compliance to the Hawthorn effect [17]. Patients were excluded if found to be hypersensitive to any component of the combination therapy or clinically judged unsuitable for eradication therapy. Ethical approval for the study was obtained from the Ethics Committee, The Queen's University of Belfast, Northern Ireland.

Methodology

Following diagnosis and enrolment into the study, patients were prescribed a 1 week regimen of lansoprazole 30 mg once daily, amoxicillin 1 g twice daily, and clarithromycin 500 mg twice daily. Lansoprazole was the selected proton pump inhibitor as it was considered to be the most cost-effective agent at the time of the study. Using a sealed envelope technique [18] patients were randomly assigned to either the control group or the intervention group.

Patient groups

Patients in the intervention group received their medicines via the Hospital Pharmacy and on receipt of their medicines each patient was counselled by the same hospital pharmacist on: their disease and the importance of

eradication of the organism; the medicines to be taken, including possible side-effects; the importance of compliance with the prescribed dosage regimen. In addition the intervention patients were given a patient information leaflet (Figure 1) about their medicines and the need for *H. pylori* eradication. They were also given a compliance diary chart (Figure 2). Intervention group patients were also telephoned 3 days after the initiation of therapy to provide further counselling on the importance of medication compliance.

Control group patients were treated according to normal hospital procedures. They were given a letter to be taken to their GP, with the recommendation that the triple therapy regimen detailed above be prescribed, together with a standard letter then in use in the department which explained the nature of the infection, the need for treatment and importance of compliance.

Assessment of H. pylori status

All patients, as was the usual practice, were asked to return to the hospital for a urea breath test, 4–6 weeks after the treatment regimen had finished, to confirm whether eradication had been successful. Eradication was defined as absence of *H. pylori* as judged by the urea breath test [19, 20].

Assessment of adverse drug reactions

All patients, in both intervention and control groups, were contacted by telephone by the same hospital pharmacist (structured questionnaire) approximately 10 days post endoscopy and asked about any adverse effects experienced during the eradication therapy, such as nausea, vomiting, diarrhoea, taste disturbance, abdominal pain, headache, itching or rash.

Assessment of compliance

Compliance was measured by two indirect techniques in both groups, i.e. patient interview by telephone (structured questionnaire) after completion of the *H. pylori* eradication therapy and pill counts (patients were asked to bring unused tablets and capsules when they returned to the hospital to have a urea breath test performed). Using these techniques the number of doses missed was recorded.

Assessment of clinical outcome measures

Patient response to the therapy was assessed using the following parameters: severity of dyspeptic symptoms and use of antisecretory medication after eradication therapy. A modified version of the Gastrointestinal Symptom Rating Scale [21] was used to assess the presence and

Antrim Area Hospital
 Department of Pharmacy
Helicobacter pylori treatment
What is *Helicobacter pylori*?
Helicobacter pylori is a bacteria which is present in the stomach of 20–40% of people. Your investigations for indigestion have shown changes in your stomach or duodenum due to the presence of the bacteria.
 Although in many people it gives no symptoms, its presence has recently been associated with the development of inflammation (for example, heart-burn) and ulcers.
 It is recommended that you receive treatment using at least two antibiotics to kill this bacteria.
Inflammation or ulceration normally disappears quickly after treatment is completed. This will eliminate your need for treatment in the future.
 A simple breath test should be carried out 6-8 weeks after completion of your treatment to check if the bacteria have been killed off completely.
About your treatment.
 You must take your medicine at regular intervals as prescribed.
 You must complete the prescribed course.
 If you miss a dose of any of your medicines, take it as soon as you remember.
 All medicines should be taken prior to a meal with a glass of water.
If you do not complete the course, or miss doses, the treatment may not be successful and your symptoms are likely to return.
 Antibiotics may cause certain side-effects such as nausea or diarrhoea. These are usually mild and settle once the treatment is finished.
 Please bring any unused tablets with you on the next visit.

Figure 1 Information sheet given to intervention patients.

Please tick (✓) in the appropriate box when you take the dose.

	Bottle No. 1 Clarithromycin 2 Capsules each dose		Bottle No. 2 Amoxicillin 2 Capsules each dose		Bottle No. 3 Lansoprazole 1 tablet each dose
	Morning	Evening	Morning	Evening	Morning
Day one					
Day two					
Day three					
Day four					
Day five					
Day six					
Day seven					

Figure 2 Patient's diary chart given to patients in the intervention group.

severity of dyspeptic symptoms, including epigastric pain or discomfort, heartburn, nausea, vomiting and wind. The presence and severity of the dyspeptic symptoms were judged by the patient. The following scoring system was used: no symptoms, score one, mild symptoms, score two,

moderate symptoms, score three and severe symptoms, score four. Patients were interviewed on the day of endoscopy and 1 month and 6 months after completion of *H. pylori* eradication therapy by the same interviewer (hospital pharmacist) using a standard questionnaire. They were also asked at the 6 month interview if they had consulted their GP for dyspeptic symptoms during the past 6 months.

Statistical analysis

Data were coded and entered into a desktop computer and analysed using SPSS (Version 7). The chi-squared test and the Fisher's exact test were used to compare non-continuous variables as appropriate. Continuous variables were analysed using the independent Student's *t*-test. In addition to comparing the control and intervention groups, symptoms were compared in the patients who had *H. pylori* eradicated vs those in patients in which *H. pylori* persisted. The Sign test was used to compare the severity of the dyspeptic symptoms 1 month and 6 months after completion of *H. pylori* eradication therapy. *P* values <0.05 were considered significant.

Results

Patient characteristics

Eighty patients fulfilled the entrance criteria and were randomly assigned to the intervention and control groups. Two patients in the intervention group were excluded, one because of an adverse drug reaction causing discontinuation of therapy and a second for failing to attend for the urea breath test after three appointments. Two patients were also excluded from the control group one because of allergy to penicillin and a second because the GP prescribed a longer eradication treatment regimen (2 weeks). Data from 38 patients in each group were therefore suitable for evaluation.

Table 1 summarizes the demography of patients participating in the study. The mean (\pm s.d.) age of the intervention group was 49.3 (\pm 16.3) ranging from 22 to 85 years compared with 50.7 (\pm 15.7) ranging from 20 to 82 years in the control group ($P=0.71$). The majority of patients in both groups were male (73.7% in the intervention compared to 68.4% in the control group; $P=0.80$). Patients in both groups were similar in terms of smoking ($P=0.29$) and although there was an increased reported alcohol consumption in the intervention group, this did not reach statistical significance ($P=0.06$).

The median duration of dyspeptic symptoms prior to eradication therapy was similar in both groups (48 months in the control group and 46 in the intervention group; $P=0.41$; Table 2).

Table 1 Demographic details of the study patients.

	Control	Intervention	P value
Number of patients	38	38	
Age (years)			
mean (\pm s.d.)	50.7 (\pm 15.7)	49.3 (\pm 16.3)	0.705§
range	(25–81)	(21–83)	
Sex (%)			0.800†
Female	12 (31.6%)	10 (26.3%)	
Male	26 (68.4%)	28 (73.7%)	
Social habits			
Smoking			0.287†
current	20 (52.6%)	21 (55.3%)	
former	8 (13.2%)	12 (31.6%)	
never	10 (34.2%)	5 (13.2%)	
Alcohol intake			0.060†
weekly	15 (39.5%)	23 (60.5%)	
occasionally	5 (13.2%)	7 (18.4%)	
none	18 (47.4%)	8 (21.1%)	

†chi-squared test; §Student's *t*-test.

H. pylori status and eradication rate

Of the 38 patients in the intervention group, 36 were urea breath test negative while of the 38 patients in the control group, only 28 patients were urea breath test negative, i.e. the eradication rate was 94.7% in the intervention compared with 73.7% in the control group (95% CIs of difference: 5.3%, 36.7%; $P=0.027$). The overall (intervention and control, $n=76$) eradication rate achieved using this combination therapy containing amoxicillin, clarithromycin and lansoprazole for 1 week was 84.2% (i.e. 64 eradicated; 12 persistent).

Adverse drug reactions

A number of patients in both groups reported that they experienced adverse effects during *H. pylori* eradication therapy, 17 patients (44.7%) in the control group compared with 19 (50%) in the intervention (Table 3, $P=0.81$). The most frequent adverse drug reactions were diarrhoea and taste disturbance.

Counselling and compliance rate

The average time (\pm s.d.) spent counselling each patient by a hospital pharmacist was 9.5 ± 2.3 min. This resulted in a 100% compliance rate (Table 4) being recorded in 92.1%

Table 2 Diagnoses, antisecretory medications and duration of dyspeptic symptoms prior to eradication therapy.

	Control (n = 38)	Intervention (n = 38)	P value
Diagnosis			
Duodenal ulcer (DU)	15 (39.5%)	13 (34.2%)	
Gastric ulcer (GU)	5 (13.1%)	2 (5.3%)	
DU and GU	2 (5.3%)	5 (13.2%)	
Duodenitis	8 (21.0%)	10 (26.3%)	
Gastritis	2 (5.3%)	1 (2.6%)	
Duodenitis and gastritis	6 (15.8%)	7 (18.4%)	
Antisecretory medications used	38	38	
Cimetidine	8	13	
Lansoprazole	2	1	
Nizatidine	5	6	
Omeprazole	5	7	
Ranitidine	18	11	
Duration of antisecretory medication usage (months)			
mean (\pm s.d.)	40.4 (\pm 5.6)	38.9 (\pm 3.9)	0.199§
range	18–72	12–96	
Duration of dyspeptic symptoms (months)			
median	48	46	0.412*
interquartile range	44.0–50.5	42.7–49.0	

§Student's *t*-test; *Mann–Whitney *U*-test.

Table 3 Adverse drug reactions (ADRs) reported by the patients.

	Control	Intervention	P value
Number of patients who experienced an ADR	17 (44.7%)	19 (50.0%)	0.810†
ADRs reported			
Abdominal pain	1 (2.6%)	3 (7.9%)	
Diarrhoea	4 (10.5%)	8 (21.0%)	
Headache	2 (5.3%)	4 (10.5%)	
Loose stool	6 (15.8%)	2 (5.3%)	
Itching	0	1 (2.6%)	
Metallic taste	6 (15.8%)	7 (18.4%)	
Nausea	1 (2.6%)	4 (10.5%)	
Rash	1 (2.6%)	2 (5.3%)	
Sore mouth	3 (7.9%)	3 (7.9%)	
Tired	4 (10.5%)	2 (5.3%)	
Vomiting	1 (2.6%)	3 (7.9%)	

†Chi-squared test.

of the patients in the intervention group. The equivalent number of patients with 100% compliance in the control was much lower (23.7%; 95% CIs of the difference: 52.3, 84.5%; $P < 0.001$). All *H. pylori* persistent patients took less than 60% of their prescribed regimen, while all eradicated patients took more than 65% of their prescribed medication.

Clinical outcome measures

Dyspeptic symptoms At the 1 month follow-up the severity scores for individual dyspeptic symptoms were, as expected, much lower for the patients in whom *H. pylori* had been successfully eradicated (Table 5). The differences in the severity scores of epigastric discomfort, heartburn, nausea, vomiting and wind were statistically significant ($P < 0.001$). In the *H. pylori* persistent patients the severity scores for nausea and vomiting were, however, statistically lower ($P < 0.001$) after *H. pylori* eradication therapy than before, while the severity scores for epigastric discomfort, heartburn and wind were not statistically different ($P > 0.05$). The same results were found at the 6 month follow-up in the *H. pylori* eradicated patients ($P < 0.001$) with little more reduction in the severity scores for epigastric discomfort, heartburn, nausea, vomiting and wind. In *H. pylori* persistent patients, at the 6 month follow-up the severity scores for epigastric discomfort heartburn, nausea, vomiting, and wind had almost returned to baseline ($P > 0.05$).

In addition, at the 6 month follow-up, the incidence of epigastric discomfort had decreased from 93.8% before treatment to 1.6%; heartburn from 75% to 3.2%; nausea from 55% to 0%; vomiting from 48.4% to 0%; and wind from 46.8% to 0% in *H. pylori* eradicated patients.

Table 4 Doses missed during the eradication therapy.

	Control	Intervention	P value
Number of patients who took all prescribed doses	9 (23.7%)	35 (92.1%)	< 0.001 †
Number of patients who missed the following number of doses			
One dose	6 (15.8%)	1 (2.6%)	
Two doses	4 (10.5%)	0	
Three doses	5 (13.2%)	0	
Four doses	3 (21.4%)	0	
Five doses	1 (2.6%)	0	
Six doses	1 (2.6%)	0	
Seven doses	2 (5.3%)	0	
Eight doses	5 (13.2%)	1 (2.6%)	
Nine doses	1 (2.6%)	1 (2.6%)	
Ten doses	1 (2.6%)	0	

†Chi-squared test.

In *H. pylori* persistent patients, the number of patients remained similar ($P > 0.05$) for all symptoms at the 6 month follow-up. However, at the 1 month follow-up, the number of patients with nausea and vomiting had decreased significantly ($P < 0.001$).

Antisecretory medications usage

The mean duration of prescribed antisecretory medications which were most commonly H₂-receptor antagonists prior to entry into the study was similar for both groups (40.4 months in the control group *vs* 38.9 in the intervention group; Tables 2, $P = 0.199$). At the 1 month follow-up, the usage of antisecretory medications was significantly reduced in all *H. pylori* eradicated patients compared with *H. pylori* persistent patients ($P < 0.001$). At the 6 month follow-up usage of antisecretory medications was eliminated in all *H. pylori* eradicated patients except two, whilst all *H. pylori* persistent patients continued to receive antisecretory medication. Again the difference was statistically significant ($P < 0.001$).

Visit to GPs

At the 6 month follow-up, *H. pylori* persistent patients were much more likely to have consulted their GPs for dyspeptic symptoms (91.7% of patients) compared with the *H. pylori* eradicated patients (4.7%; $P < 0.001$). In the *H. pylori* persistent group, seven patients had consulted their GPs once during the 6 month follow-up, two patients twice and another two patients three times, while the three that consulted their GPs in the *H. pylori* eradicated group had done so only once.

Table 5 Dyspeptic symptoms assessment.

Dyspeptic symptoms	Time*	H. pylori eradicated Follow-up pre and post treatment (n = 64)			H. pylori persistent Follow-up pre and post treatment (n = 12)		
		0	1	6	0	1	6
Epigastric pain							
nil		4	61	63	2	2	2
mild		1	3	1	0	0	0
moderate		9	0	0	1	2	2
severe		50	0	0	9	8	8
% with symptom		93.8%	4.7%	1.6%	83.3%	83.3%	83.3%
Heartburn							
nil		16	50	61	3	3	3
mild		1	14	3	0	0	0
moderate		7	0	0	1	2	0
severe		40	0	0	8	7	9
% with symptom		75%	21.9%	3.2%	75%	75%	75%
Nausea							
nil		29	60	64	5	7	3
mild		15	3	0	3	2	3
moderate		10	1	0	3	2	2
severe		10	0	0	2	1	4
% with symptom		55%	4.7%	0%	66.7%	41.7%	75%
Vomiting							
nil		33	63	64	6	12	6
mild		22	1	0	5	0	5
moderate		7	0	0	1	0	1
severe		2	0	0	0	0	0
% with symptom		48.4%	1.6%	0%	50%	0%	50%
Wind							
nil		30	52	64	4	4	4
mild		3	12	0	0	0	0
moderate		9	0	0	3	2	2
severe		22	0	0	5	6	6
% with symptom		46.8%	18.8%	0%	66.7%	66.7%	66.7%

*0: symptoms severity before eradication therapy; 1, 6: symptoms severity 1 and 6 months after completion of eradication therapy.

Treatment costs

The direct costs of a 1 week course of the triple therapy regimen, other expenses involving the urea breath test and patient counselling together with the financial implications of a second eradication programme are summarized in Table 6. The community-based costs for 1 year of treatment with the antisecretory medications that were being used by patients before eradication therapy, with the exception of cimetidine therapy, far exceeded the eradication costs. In this study, of the 64 *H. pylori* eradicated patients 62 were able to completely stop antisecretory medications.

Overall costs

In economic terms the present data indicate that £8402 would be needed to eradicate *H. pylori* in 100 patients

using the study treatment regimen plus counselling, while an additional £3026 would be needed to eradicate *H. pylori* in 100 patients using the same eradication therapy without counselling. Patient counselling and follow-up therefore appears to be a cost-effective option.

Discussion

Guidelines identifying which patients, infected with *Helicobacter*, should be given eradication treatment have been published [22]. Of the many treatment regimes reported, proton pump inhibitor-based triple therapies for a period of 1 week appear, at present, to represent the optimal therapeutic option for eradication of *H. pylori* [23]. Inevitably most regimes show variation in reported eradication rates, and this has been particularly marked for dual therapy regimes with a proton pump inhibitor and amoxicillin [24]. It is likely that variations in reported

Table 6 Cost of *H. pylori* eradication.

Cost element	Cost (£)*
Expenses per successful eradicated case	
Eradication therapy	42.3
Urea breath test (¹³ C test plus labour)	32
Patient counselling (average time spent + phone call + diary card)	3
Total	77.3
Expenses per one failure case	
Eradication therapy	42.3
Urea breath test (¹³ C test plus labour)	32
GP consultations (average)	52.3
Another course of eradication therapy	42.3
Another urea breath test	32
Total	200.9

*Costs obtained from Monthly Index of Medical Specialties (MIMS), Hospital Trust and Health Board sources.

success rates are related to differences in patient populations, including their compliance, variability in the details of trial design and the prevalence of antimicrobial resistance, particularly to metronidazole. The view has been expressed that clinical practice may be at variance with results of clinical trials of *Helicobacter* eradication [10] though others have disagreed [25]. The experience in this hospital has been that it is difficult to reproduce the effectiveness of clinical trial regimes for eradication of *Helicobacter*. In the present population metronidazole resistance was present in 24% of *Helicobacter* cultures (unpublished data), but it was felt that other factors may have contributed to the difficulties in replicating clinical trial results.

The aim of the present study was to determine if the effectiveness of a triple therapy regimen, which did not include a nitro-imidazole, could be enhanced by paying particular attention to improving patient compliance. This has been recognized as an important issue, which impacts on the eradication rate achieved by different types of *H. pylori* eradication therapy [26, 27]. In this study patients in the intervention group received detailed counselling from a pharmacist about the rationale for treatment, the possible side-effects and the importance of good compliance. These patients were also provided with the medication by the hospital pharmacist, with the required instructions of dosing at the time of the initial counselling session. The control population received a standard letter explaining the nature of the infection and the need for treatment. They were asked to contact their GP to obtain the necessary prescription. The study demonstrated the value of patient counselling since the intervention group were significantly more compliant than those in the control group (92.1% vs 23.7%, who took all prescribed doses;

$P < 0.001$). All patients who showed a failure of eradication had taken less than 60% of their prescribed dosage regime. As a result, eradication rates were significantly higher in the intervention group (94.7% compared with 73.7% in the control group; $P = 0.027$). Before the study started, the eradication rate in our hospital, using the same regime, was 72% in 86 patients (unpublished data). The higher eradication rate achieved in the intervention group would appear to be due to the influence of patient counselling about their disease, drug treatment and the resultant good compliance with the prescribed regime. There may also have been an effect of the further checks undertaken in the intervention group during follow-up telephone calls. As a result the eradication rate was significantly improved to as good as, or better than, appropriate clinical trials [28] indicating that in clinical practice it is important to try to duplicate the instruction, education and counselling which takes place in a clinical trial.

As expected, symptoms in patients in whom *H. pylori* was successfully eradicated were significantly improved. The number of patients with dyspeptic symptoms was significantly reduced, and more importantly the severity of each of the measured dyspeptic symptoms was significantly reduced, both 1 month and 6 months after treatment. *H. pylori* persistent patients showed slight improvements in nausea and vomiting at 1 month, but by 6 months symptoms, frequency and severity were unchanged from the pre-treatment levels. Similar results have been reported by other investigators [29], and indeed it has been suggested that symptom control is a useful surrogate for confirming that eradication has taken place [30].

In this study *H. pylori* persistent patients continued to require antisecretory medications, while those who were eradicated did not, and as other studies have shown had much reduced contact with their GPs following eradication [31]. This has significant cost implications since most of the difference in costs of different regimes is related to the cost of failure of eradication. The appropriateness of using lansoprazole 30 mg daily in our chosen regime may be questioned since using a twice daily dose, as with the other proton pump inhibitors, may be more effective. Others have, however, found good eradication rates with once daily proton pump regimens [32, 33].

The possible suboptimal nature of the regime may have permitted the benefit of detailed patient counselling to become apparent, and indicates that a highly acceptable eradication rate can be achieved with such a regime if careful attention is paid to patient counselling and compliance. In the present study, adverse drug reactions were generally mild in nature and well tolerated.

The present study suggests that variations in *Helicobacter* eradication rates may be due to factors other than the drug regime chosen, and that patient counselling can have

a significant impact on improving success rates. It would seem important that details of the instructions and information given to patients together with subsequent monitoring should be included in clinical trial reports. The present study reinforces the view that a central part of any eradication regime must be careful explanation of the rationale of treatment, the need for full compliance and discussion of possible side-effects with the patient [33, 34].

In conclusion, the results of this study document the significant difference between the routine clinical practice (control group) and counselling enhanced treatment (intervention group) and highlight the urgent need for structured patient counselling to be introduced into routine clinical practice. Combined with well structured patient counselling, a lansoprazole, amoxicillin and clarithromycin combination can result in excellent compliance and highly efficient, cost-effective eradication of *H. pylori*.

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